Medical Imaging Technology

WG 2 - Final Working Group Report

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Preface

This report of the "Image Generation and Capture" Working Group is one of five that comprise the Medical Imaging Technology Roadmap. This Roadmap is intended to provide a market-driven forecast of technologies needed to improve patient care and enhance the global competitiveness of the Canadian medical imaging sector. The Roadmap is expected to strengthen technology development, diffusion and adaptation, and help to guide public and private sector decision making with respect to product development, investment, human resources and other policy areas.

The 14-person Medical Imaging Technology Roadmap Steering Committee provided overall direction and guidance for this project (see Appendix A for the membership list). Steering Committee members represent companies, researchers, clinicians and government organizations involved with the Canadian medical imaging sector. Industry Canada is the catalyst and facilitator of the roadmapping process. A total of 75 people representing more than 50 organizations have participated in the project, creating opportunities for potential alliances and information sharing.

Visit the project Web site at http://strategis.ic.gc/medimage to view the following reports:

- WG1: Future Needs for Medical Imaging in Health Care (2000);
- WG3: Transmission and Connectivity (2001);
- WG4: Image Analysis and Visualization (2000);
- WG5: Emerging Technologies with Emphasis on Photonics (2001); and
- ORTECH: Medical Imaging: Discussion Paper (1999).

These reports are available in French at http://strategis.ic.gc/imagemed.

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EXECUTIVE SUMMARY

Introduction

This report of the "Image Generation and Capture" Working Group identifies and describes critical technologies in seven key groupings within medical imaging: radiography and fluoroscopy, computed tomography (CT), magnetic resonance imaging (MRI), image-guided surgery, nuclear imaging, magnetoencephalography (MEG) and electroencephalography (EEG) and ultrasound.

Radiography and Fluorscopy

The development and enhancement of **flat-panel image detectors** is of significant interest to both radiography and fluoroscopy. The size of the specific active matrix (up to 17" x 17") is a key consideration, as is the level of emitted noise (low-noise readout integrated circuits). Tab bonding promises a satisfying solution to the problem of providing reliable, high-density connections to active matrices, while hermetically sealed cesium iodide scintillators are broadly applicable to radiography and fluoroscopy, as well as to other medical imaging modalities, as a means of securing the best possible image quality.

Large-area deposited direct converters represent a critical opportunity in **radiography and fluoroscopy systems**, whereby Canadian industry could produce cost-effective X-ray flat-panel imagers to compete with the conventional approach, which uses cesium iodide phosphor layers. Important systems factors include the speed (high-speed digital data connections and digital image processing) and the quality of resolution (high-resolution printers, monitors and flat-panel displays). Determining objective image quality of radiography and fluoroscopy systems can be done through characterization tools and phantoms.

The development of **software**, whether the aim is to provide a more user-friendly interface or to integrate separate technologies, provides another opportunity to anticipate and meet clinician needs. Specifically, an X-ray generator interface, carefully designed to take into account clinical needs and methodologies, is highly desirable, as is the integration of flat-panel detectors into MRI.

Computed Tomography

CT is widely used in Canada and the existing CT capacity is large. Improvements to CT can therefore have a very significant clinical impact. **Cardiac-gated helical CT** may offer sufficient spatial and contrast resolution in coronary imaging to replace diagnostic X-ray coronary angiography. **Flat-panel CT** has the potential to allow near real-time visualization of complete body regions with isometric spatial resolution.

Magnetic Resonance Imaging

Clinicians are constantly finding new applications for MRI. There is an opportunity to enhance MRI **hardware**'s usefulness through coil improvements, such as gradient coils with higher maximum gradient levels and faster slew rates, and specialized radio frequency coils. New MRI systems for specific uses, which largely use core MRI technology while being tailored to a particular clinical speciality (e.g. rheumatology), could be sized to fit into a clinician's office. Neurosurgeons could benefit from new permanent open-magnet MRI systems to allow real-time interventional neurosurgery. Very high-field MRI units (3 tesla or higher) are in demand by clinical researchers, and will be increasingly driven by clinician requirements for more diagnostic information.

Functional MRI (fMRI) could be made more useful to researchers and physicians in the field of brain mapping through the development of image analysis software for the manipulation and interpretation of fMRI data. *In vivo* magnetic resonance spectroscopy (MRS), the use of which has become much more common since it became a reimbursable exam in the United States, is of value for physiological studies on any living system to determine the concentration of important chemicals in the body. Non-invasive magnetic resonance coronary angiography should ultimately eliminate X-ray diagnostic coronary angiography, and could have a tremendous impact in Canada due to the pervasiveness of cardiovascular disease. A key goal of MRI is to enable image viewing anywhere in the world through the use of acquisition software and a secure connection capable of transmitting images as full, lossless data sets.

Diffusion and perfusion MRI is a critical **clinical** technology. Faster gradients and new pulse sequences, as well as solving the magnetic susceptibility problem associated with echo planar imaging sequences, would make diffusion and perfusion MRI even more useful as a tool in stroke management.

Image-Guided Surgery

Whether image-guided surgery **software packages** are for image fusion or real-time viewing, the key is to keep them user-friendly even as they pursue gains in the speed and accuracy of image capture and transmission. **Magnets specialized for surgical procedures** offer the significant advantage that the patient can sit up during the procedure, but they must be designed to keep operating time in check and to allow a clear view of the patient at all times. **Operating room suites designed for intraoperative MRI** can allow surgeons to access MRI during surgery, and turn-key solutions for hospitals can be designed that enable scanning to be done on both operating room and diagnostic patients, without compromising the sterile environment required for surgery.

Nuclear Imaging

Nuclear imaging **software** needs to be capable of scanning a large area (up to the whole body) in a short time while relying on sophisticated correction methods (e.g. camera quality control) based on efficient algorithms. As such, it must be able to handle very large sets of data, and both process and analyze very complex 3-D data.

An important consideration for nuclear imaging **hardware** is that the scintillation camera seems to be reaching the limit of cost-effective performance improvement, though there are still some possible improvements to be gained by further developing certain aspects, such as improving image contrast through enhancing energy resolution. Meanwhile, semiconductor cameras are not yet being clinically applied. Semiconductor cameras can be cost-prohibitive, and their future is still unclear. These cameras represent a kind of nuclear imaging hardware likely to undergo further improvements, as do positron emission tomography (PET), attenuation and scatter correction, and image fusion.

Clinical radiopharmaceutical agents administered to patients to examine physiological functions and identify organ disease are becoming more specialized (i.e. disease- and organ-specific). PET and single photon emission tomography (SPECT) radiopharmaceutical "tracers" have come into wide use, though only PET can quantify some key metabolic measurements in absolute physiological terms and offer the most cost-effective means of staging many cancers.

Electroencephalography & Magnetoencephalography

Though **electroencephalography (EEG)** clearly dominates in clinical practice, **magnetoencephalography (MEG)**, which has been and continues to be primarily limited to research activities, has undergone significant improvements over the last few years (e.g. drastic cuts in the necessary recording time and greater system flexibility) and has now arrived at the point at which it can be put into clinical use. However, MEG technology, to a large extent because of its much higher cost, will not replace EEG technology, but rather will complement it in clinical settings. EEG, while relatively mature, still has the potential to be improved through advances in hardware, and especially through enhanced capability to handle high data volumes.

Ultrasound

A dose of an ultrasound **contrast agent** currently costs approximately as much as the ultrasound exam itself. This cost issue is significant and will cease to be so only when studies have demonstrated that this expense can obviate the need to resort to more expensive procedures. Adding contrast agents to ultrasound expands the range (i.e. arteriolar and capillary) and timeliness (i.e. real time) of available information to a level unattainable through any other current imaging procedure. There is an impressive range of available contrast agents, and their characteristics and formulations continue to be improved.

Since ultrasound **scanners** are mature to the point that the limits of physics will soon be reached, factors such as cost and user-friendliness will become the most significant differentiating characteristic in a purchasing decision. Though relatively stable from a technology standpoint, this highly popular modality can certainly still be improved, such as by gaining better resolution through the use of transducers with 1.5- and 2-D arrays. An important change in ultrasound scanners is that they can no longer be considered stand-alone systems. They must be capable of communicating large amounts of digital data to other systems. Portability is another important development, bringing the possibility of a low-cost scanner in every doctor's office a step closer to reality.

Though ultrasound scanners have made tremendous contributions to diagnostic imaging, deficiencies in ergonomics have exacted a high price from sonographers, causing large numbers of serious repetitive strain injuries and lost work days. A **scanner/sonographer interface** designed to benefit from the findings of ergonomics research could have a significant positive impact on health care budgets and personnel. As the costs of repetitive strain injury become more widely known, scanner purchase decisions will become increasingly affected by ergonomic specifications, which, in comparison to other scanner specifications, have changed very little since the advent of real-time sonography.

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INTRODUCTION

Scope

The scope of the "Image Generation and Capture" Working Group was to identify and describe enabling technologies that need to be developed to fulfil future patient and market needs with respect to image generation and capture. The modalities that were explored include X-rays, fluoroscopy, computed tomography (CT), magnetic resonance imaging (MRI), functional magnetic resonance imaging (fMRI), image-guided surgery, nuclear imaging, magnetoencephalography (MEG), electroencephalography (EEG) and ultrasound.

Membership

The "Image Generation and Capture" Working Group consists of clinicians and representatives of the corporate sector and the research community. Appendix B contains a complete membership list.

Outline

The body of this report is divided into seven sections:

- radiography and fluoroscopy;
- computed tomography;
- magnetic resonance imaging;
- image-guided surgery;
- nuclear imaging;
- electrophysiological measurements (MEG and EEG); and
- ultrasound.

The Working Group used a critical technology template (see Appendix C) to organize the information in each section. However, the template was modified when the need was compelling.

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RADIOGRAPHY AND FLUOROSCOPY
FLAT-PANEL IMAGE DETECTORS

- Specific Active Matrix Covering up to 17" X 17"
- Low-noise Readout Integrated Circuits
- High-Density Connections
- Hermetically-sealed Cesium Iodide Scintillators and Relevant Processing Technologies

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Specific Active Matrix Covering up to 17" X 17"

1. GOALS

Performance goals are driven by the size of the matrix, the target clinical applications, and the complexity of the active matrix structure. All of the above considerations influence the matrix performances in terms of noise, dynamic range and maximum switching speed.

Depending on the clinical application, the performance goals will be different.

1.1 Radiography
The challenge is different for radiography than it is for fluoroscopy. Since the application does not require high-speed readout and does not operate at low dose, the matrix structure itself does not have to be optimized very much. Here the size of the panel is the main concern. The coverage area has to be as large as 17" x 17". The main goal is to produce large panels at the lowest cost.

1.2 Fluoroscopy
For fluoroscopy, matrices are reasonably small (9" x 9" to 12" x12"), so the main concerns are the noise and the readout speed. For the matrix, this translates into making low-noise panels that can be read quickly (30 and 60 frames per second [fps]). The matrix is one of the largest contributors of noise in a flat-panel detector. Generating only little noise and fast, readable panels is the main goal and it is achievable by optimizing the panel structure. Since these criteria are not mandatory for the computer industry, the driving force of the market, cost is suffering.

2. DESCRIPTION

A specific active matrix collects charges from a compatible X-ray conversion layer (such as cesium iodide, amorphous selenium alloys, cadmium tellurium, cadmium-zinc-telluride, lead iodide or mercuric iodide). It employs the thin-film active matrix technology. Each pixel of the array contains a charge collection element or elements and, depending on the energy converter associated with this panel, can also include other elements such as a photo converter (photodiode) or protecting elements (e.g. diode, transistors). In the medical field these active matrices are used in switching mode. Panel sizes can vary from 9" x 9" to 17" x 17", depending on the applications.

3. IMPORTANCE

This technology is essential to make any X-ray flat-panel imagers. All flat-panel image detector manufacturers need this technology. The source of supply of these panels is critical. Many large producers of active matrices are not really interested in the potential market of the medical industry, considering it too small to put in the effort.

The approach taken by several big original equipment manufacturers (OEMs) in the medical field was to produce such panels themselves or buy a producer of active matrices. The other manufacturers of flat-panel detectors have to rely on alliances with less important manufacturers of panels and then do not have access to the latest technology available in this field (e.g. large panels, high yield).

4. CLINICAL REQUIREMENTS

Coverage area (panel size), good spatial resolution (pixel size), dynamic range (charge storage capacity), real-time imaging, low noise (panel structure) and a low number of defects (pixel, lines) are all important.

5. ALTERNATIVES

For small flat-panel detectors, a thin-film transistor active matrix can be substituted for an array of small photo-sensitive detectors (e.g. charge-coupled devices) coupled to a scintillator through tapered optical fibers.

6. MATURITY AND RISK

Even though active matrix is becoming more and more mature in the computer industry, it is dangerous to directly transpose this maturity to the medical field since this technology is not used in the same way. The risk, although not very high, is there.

7. AVAILABILITY

Availability of active matrix is a very important issue. Major players developing and producing this technology are known from the computer industries. But, as mentioned above, most of them are not really interested in the medical market. Acquisitions or development of the technology itself are solutions for OEMs of flat-panel detectors. Investment in both cases is important and may not be possible for all the OEMs.

8. BREADTH OF APPLICATION

The technology is applicable to all medical applications in which X-rays are used, for real-time applications as well as static or snapshot situations. The technology is also applicable to nondestructive testing, food inspection, lumber grading and protein crystallography, among others.

9. COST-BENEFIT ANALYSIS

Large investments are required to develop or even acquire such technology, especially for the largest panel size. The medical market is not big enough to justify all this investment. It must also serve other industries, such as computer and aeronautics.

10. CONTACTS

Luc Laperrière, Anrad Corp., St-Laurent, Quebec (see Appendix B for further information): laperril@anrad.com.

Low-noise Readout Integrated Circuits

1. GOALS

An application-specific integrated circuit (ASIC) is driven by noise, speed and dynamic range. The ASIC must be able to cover all the dynamic range required by the various clinical applications in which it will be used. For the most demanding applications, such as low-dose fluoroscopy, the ASIC must be very quiet while operating at high speed (30 to 60 fps). For radiography, requirements are less severe, but the ASIC still has to offer decent performance.

2. DESCRIPTION

These circuits are a means of amplifying signal and integrate charges coming from the active matrix. They typically include a low-noise pre-amplifier, a signal shaper, a sample and hold circuit, and an analog output multiplexer. It may also includes an A/D converter. It handles between 64 and 128 inputs channels. It has to be connected to an active matrix by wire bonding or by tab bonding. The substrate on which the readout ASIC is mounted also is of some importance. Ideally, the readout ASIC must be connected close to the source of the signal. Thus, the way the connections are made between the active matrix and the readout ASIC will influence the choice of substrate.

3. IMPORTANCE

These low-noise readout integrated circuits are critical because they are the primary determinants of flat-panel detector performance in terms of noise, bandwidth and dynamic range. This technology is essential for making any X-ray flat-panel imagers. If ASIC is not used, performance will suffer and costs will rise.

4. CLINICAL REQUIREMENTS

In terms of clinical requirements, the integrated circuits must be well designed to handle a broad range of cases. For the most demanding application, low-dose fluoroscopy, the contribution of the ASIC to the total noise must be minimized and the readout speed maximized. Dynamic range is another important factor to consider. Some protocols require switching from low-dose to high-dose and vice versa. The ASIC must be able to support an important range of input doses, so gain and saturation limits must be wisely selected within the ASIC.

5. ALTERNATIVES

It is possible to employ discrete components as an alternative to an ASIC. However, using discrete components will not be advantageous in terms of performance and cost. Practically speaking, there is no alternative to ASICs.

6. MATURITY AND RISK

This technology is available and mature.

7. AVAILABILITY

Most OEMs in the medical field have made or are making their own custom ASICs. Availability is not really an issue. Many other industries are using ASICs. ASIC design companies and founders are relatively easy to access.

8. BREADTH OF APPLICATION

The ASIC is optimized to operate at its best in specific conditions (at specific signal levels, frame rate and noise level). Any applications requiring similar conditions can benefit from the ASIC. Typically, since the ASIC is optimized to operate with a specific type of active matrix, most of the applications using the same active matrix will, of course, benefit from using the same ASIC. Thus, the technology is applicable to all medical applications in which X-rays are used, for real-time applications as well as static or snapshot situations.

9. COST-BENEFIT ANALYSIS

The initial cost of developing an ASIC is substantial but it is recovered by savings in production. The flat-panel detector market is certainly big enough to justify the development of such an ASIC.

10. CONTACTS

Luc Laperrière, Anrad Corp., St-Laurent, Quebec (see Appendix B for further information): laperril@anrad.com.

High-Density Connections

1. GOALS

The main performance goal of this technology is to make good and reliable connections. The possibility of being able to easily repair a connection is another important consideration. As described below, two main technologies are competing in the field of high-density connections: wire bonding and tab bonding. Tab bonding is well adapted to connections with an active matrix, so it should be able fulfil its goals.

2. DESCRIPTION

High-density connections are the means of making electrical contact between an active matrix and its peripherals. Peripherals in this case are the matrix-driving circuit and the readout ASICs. These contacts can be made by two main technologies: wire bonding and tab bonding. Wire bonding simply refers to connections made by small, thin wires. Tab bonding refers to connections made with the help of a thin film of thermo-curable material containing tiny conductive balls. Compressed and heated between two conductive pads, the small balls in this thin film will create an electrical contact in the axis of the applied pressure. The density of connections covered by both technologies is enough to support the target applications, radiography and fluoroscopy. Connection density for these applications may vary from 100 µm to 200 µm.

Tab bonding is currently used in the laptop industry. It permits connections to be reworked more easily.

3. IMPORTANCE

The way the two most important parts of a flat-panel detector — the active matrix and the low-noise integrated circuit — is of critical importance. Bad connections will result in a loss of signals and/or an increase in noise.

4. ALTERNATIVES

There is no alternative to high-density connections, since these are dictated by the size of the connections of the active matrix, which are high-density.

5. MATURITY AND RISK

In the case of both wire bonding and tab bonding, the technology is mature. As mentioned above, tab bonding is currently used in the laptop industry and is well understood and controlled. It should be the only technology used in the near future. The risk of selecting and using this technology today is low.

6. AVAILABILITY

This technology is easily available because of its origin. There is an interesting choice of machines on the market (based on automatization, size and cost).

7. BREADTH OF APPLICATION

The high-density connections technology can be directly applied to all industries dealing with high-density connections, medical or otherwise.

8. CONTACTS

Luc Laperrière, Anrad Corp., St-Laurent, Quebec (see Appendix B for further information): laperril@anrad.com.

Hermetically-sealed Cesium Iodide Scintillators and Relevant Processing Technologies

1. GOALS

- to make the best image quality for a given radiographic application, driven by customer requirements;
- the performance can and should be defined in quantitative and qualitative terms (without disclosing proprietary information related to how the layers are made, it should be very specific as to the performance of specific layers); and
- the economic impact of the layers is not only their cost but the yield with which they can be manufactured, bearing in mind that they are only one component of a very costly flat-panel system. When their process is not close to 100 percent, there will be wastage of other very expensive components (financial), time (e.g. cycle time improvements) and physical property considerations (mechanical robustness to permit operation in clinical environments where they may be bumped or even dropped, sealed from atmospheric contamination, specifically from moisture that can destroy the fluorescent properties of the layer).

2. AVAILABILITY

Hamamatsu (Japan) is an important player in the industry.

3. BREADTH OF APPLICATION

Broadly applicable to all medical procedures using X-ray imaging, possibly also including computerized tomography (CT). Also applicable to non-destructive testing and web inspection, such as food inspection, lumber grading and protein crystallography.

4. IMPACT OF STANDARDS AND REGULATIONS

None foreseen.

5. REFERENCES

Rowlands JA and J. Yorkston. 2000. "Flat-panel detectors for digital radiology," in *Medical Imaging Volume 1. Physics and Psychophysics,* eds. J Beutel, HL Kundel and RL Van Metter (SPIE: Bellingham), 223–328.

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RADIOGRAPHY AND FLUOROSCOPY SYSTEMS

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- High-resolution Monitors and Flat-panel Displays
- High-resolution Printers

Large-Area Deposited Direct Convertor

1. GOALS

- driven by customer requirements for high detective quantum efficiency devices at the appropriate X-ray energy range; and
- performance can and should be defined in quantitative and qualitative terms as the proprietary component is how to actually make these layers, not what the desired parameters are.

2. DESCRIPTION

This is a means for making X-ray-sensitive direct conversion layers that should be compatible with thin-film active matrix array technology, preferably by evaporation or other thin-film process directly onto the thin-film transistor (TFT), without thermal or other damage to the substrate. Examples are amorphous selenium alloys, CdTe, CdZnTe, TlBr, lead iodide and mercuric iodide.

3. IMPORTANCE

The technology is critical to making a cost-effective X-ray flat-panel imagers in competition with the major approach using CsI phosphor layers. The technology is critical to several national and

international companies making the direct conversion approach their preferred method.
If the technology is not available then it will be very difficult for Canadian industry to be competitive in the flat-panel sensor marketplace.

4. CLINICAL REQUIREMENTS

The technology must show high detective quantum efficiency, and be physically robust and free from lag and ghosting.

5. ALTERNATIVE

The major alternative to direct conversion layers is indirect conversion layers.

6. MATURITY AND RISK

Today, amorphous selenium layers are close to perfection in all the imaging requirements. The major deficiency of amorphous selenium is its low atomic number, which is intrinsic and cannot be improved. Other higher atomic number materials are only just starting to show some desirable imaging properties, and several major issues have to be resolved for each of the other materials before they can be regarded as practical.

7. AVAILABILITY

A major supplier of amorphous selenium layer is Anrad Corp., located in St-Laurent, Quebec. Other materials are under investigation by RMD (lead iodide), Spire Corp. (cadmium zinc telluride), the University of Connecticut (TlBr), and the Hebrew University of Jerusalem (mercuric iodide).

8. BREADTH OF APPLICATION

The technology is applicable to all medical applications in which X-rays are used, for real-time applications as well as static or snapshot situations. The technology is also applicable to non-destructive testing, food inspection, lumber grading and protein crystallography.

9. IMPACT OF STANDARDS AND REGULATIONS

International Electrotechnical Commission (IEC) and NEMA standards have to be developed, and there is a danger that major companies may seek to freeze out such technologies in favour of CsI unless vigilance is used.

10. REFERENCES

Rowlands JA and J. Yorkston. 2000. "Flat-panel detectors for digital radiology," in *Medical Imaging Volume 1. Physics and Psychophysics,* eds. J Beutel, HL Kundel and RL Van Metter (SPIE: Bellingham), 223–328.

11. CONTACTS

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High-speed Digital Data Connections

1. GOALS

1.1 Radiography

Radiographic images comprised of matrices 4000 x 4000 x 16 bits need to be transferred at rates of 1 fps or ~32 Mb/s.

Must meet electromagnetic interference standards CE MDD: IEC1000-4-2, IEC1000-4-3, IEC1000-4-4, IEC1000-4-5, IEC1000-4-6, IEC1000-4-8 and IEC1000-4-11.

1.2 Fluoroscopy and Digital Spot

Transmission of fluoroscopic and digital spot images (1024 x 1024 x 12 bits) at 30 frames per second (fps) or ~ 63 Mb/s assuming 16-bit words. Transmission at higher frame rates (60 fps) is a possible requirement. Cable length requirement of 15 m, good noise immunity from X-ray generator noise.

2. DESCRIPTION

Fibre-optic or Low-voltage Differential Signal Links

Fibre-optic links are smaller, lighter and have more physical flexibility and are a little more expensive than low-voltage differential signal links (LVDS), but this cost difference depends upon the cable length required. As the cable length increases, fibre optics becomes more economical.

Fibre optics is probably the best choice for the transfer of digital image data from the image receptor to the image processing and storage box.

For control signals related to timing of instrument functions (e.g. X-ray generators), Rs-422 or opto-coupled signals would be better.

3. IMPORTANCE

The digital image transfer link must be fast, reliable, low-noise, physically flexible and non-bulky in order to gain market acceptance and meet regulatory requirements.

The technology is essential for the operation of the image devices.

4. CLINICAL REQUIREMENTS

There are no specific clinical requirements, only the required data transmission characteristics.

5. MATURITY AND RISK

The technology today is marginally sufficient to meet the required data transmission rates over a single fibre-optic line using readily available, cost-effective components. Verification is required.

6. AVAILABILITY

One identified source of parallel to serial fibre-optic transceivers is HP/Agilent. Costs need to be contained to a level appropriate for the medical market.

7. COLLABORATORS

Nortel, JDS Uniphase, HP/Agilent.

8. REFERENCES

http://www.semiconductor.agilent.com/news/pr/06may97.html

9. CONTACTS

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High-speed Digital Imaging Processing

1. GOALS

1.1 Radiography

The radiography functions required are principally related to the operation of the sensor, as briefly outlined above.

1.2 Fluoroscopy and Digital Spot

Process and display 1024 x 1204 x 12 bit images at 30 frames per second (fps). Real-time image functions requiring implementation are edge enhancement (preferably 7 x 7 or 9 x 9 kernel size), variable frame averaging with or without motion detection, zoom, pan and gamma adjustments. Additional real-time functions needed for the image sensor include fixed-pattern gain normalization and dark current subtraction.

2. DESCRIPTION

The real-time (30 fps) fluoroscopy functions could be implemented in field-programmable gate array (FPGA) or CPLD (complex programmable logic device) hardware. It may be possible to perform the real-time functions using newer, faster processors such as Alpha, Power PC, Pentium III and higher speed/wider bus architectures. Parallel processing techniques may be feasible. The use of Harvard architecture DSPs (digital signal processor) such as the Analogic SHARC (Super Harvard Risc Computer) should also be considered.

3. IMPORTANCE

The image processing functions outlined above are considered necessary by practicing physicians and the market place.

4. MATURITY AND RISK

Hardware FPGA solutions are proven. Software multiprocessing approaches are unproven, but would be more flexible, and possibly more economical.

5. AVAILABILITY

The required technologies are readily available from Xilinx, Cypress, Analogic and other suppliers. Software operating system platforms such as RT Linux, and NT are available.

6. BREADTH OF APPLICATION

Ultrasound and other image-intensive processing (e.g. 3-D) might benefit from the technology.

7. COLLABORATORS

Semiconductor companies and community (Linux) software developers.

8. CONTACTS

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Characterization Tools, Phantoms, Software

1. GOALS

The goal is to determine objective image quality of digital radiographic and fluoroscopic systems under different X-ray fluence rates (fluoroscopy) and exposures (radiography). Image quality is also to be assessed as a function of the X-ray beam quality or spectral characteristic.

1.1 Radiography

Determine detective quantum efficiency (DQE) as a function of beam quality and exposure.

Determine modulation transfer function (MTF).

1.2 Fluoroscopy and Digital Spot

Determine DQE as a function of beam quality and exposure rate.

Determine MTF.

2. DESCRIPTION

The DQE is considered to be the most objective parameter in assessing the quality of an X-ray imaging chain.

3. IMPORTANCE

It is essential to do a quantitative assessment of the imaging performance of an X-ray imaging system..

4. ALTERNATIVES

Special phantoms.

5. MATURITY AND RISK

These tools are well understood in the academic world, but not understood well in the industrial world.

6. AVAILABILITY

Requires proper data acquisition tools and specialized software.

7. BREADTH OF APPLICATION

Applies only to photon sensors. Might be applicable to visible light systems.

8. COLLABORATORS

The universities.

9. COST-BENEFIT ANALYSIS

Proper image assessment could determine the choice of the minimum (cheapest) imaging technology to obtain the required imaging performance (DQE).

10. CONTACTS

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High-resolution Monitors and Flat-panel Displays

1. GOALS

Determine cost/performance trade-offs of different digital image display technologies. Evaluate novel display technologies.

2. DESCRIPTION

Cathode-ray tube (CRT)-based monitors cannot deliver an image having the same brightness as one obtained using a view box and radiographic film. It is unknown whether this is a real deficiency or just a learned preference of radiologists.

Lower-cost "colour" monitors with masks have relatively low luminance. Does software windowing and leveling obviate the brightness problem or is there a flaw with the window/leveling paradigm? Do radiologists use window/leveling or is it considered too onerous?

Monochromatic monitors should provide the brightest and highest resolution images. Such modern monitors also provide for dynamic adjustment of electron beam focussing and timing to optimize the image over the entire monitor face.

3. IMPORTANCE

The clinical acceptability of different types of digital image display methods needs to be understood.

4. ALTERNATIVES

New types of display technologies and physics are being developed. The new brighter display methods need to be enumerated and evaluated.

Some examples of alternatives to CRT display technology are:

- liquid crystal display (LCD);
- field emission displays;
- vacuum fluorescent displays;
- plasma displays;
- thin-film electroluminescent displays (TFEL);
- light emitting diode arrays (LED);
- electrochromic displays (ECD);
- thermochromic displays (TCD);
- organic luminescent displays (OELD);
- plasma addressed liquid crystal displays (PALC);
- microdisplays on CMOS backplanes; and
- micro-optical electromechanical systems (MOEMS).

5. MATURITY AND RISK

CRT technology is mature. Others are in various states of development (product level to research prototypes only).

6. AVAILABILITY

Readily available prototypes for certain technologies.

7. CONTACTS

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High-resolution Printers

1. GOALS

Evaluate different X-ray image printing technologies suitable for low- and high-end digital X-ray imaging systems.

2. DESCRIPTION

Printing technologies include wet-film printers using laser print engines, dry-film printers using laser print engines, xerographic technology using laser print engines, ion printing methods, ink jet methods, and thermal technology.

The speed, cost and environmental impact of the printing are considerations.

3. IMPORTANCE

Medium.

4. CLINICAL REQUIREMENTS

An understanding of the viewing preferences of radiologists and the criteria (objective) important to the radiologist.

5. COLLABORATORS

Radiologists.

6. COST-BENEFIT ANALYSIS

To be determined.

7. CONTACTS

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Medical Imaging Technology

WG 2 - Final Working Group Report

RADIOGRAPHY AND FLUOROSCOPY SOFTWARE

▸ X-ray Generator Interface
▸ Integration of Flat-panel Detectors to Magnetic Resonance Imaging

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X-ray Generator Interface

1. GOALS

Optimize X-ray generator interface with digital acquisition systems and implement a unified system user interface.

2. DESCRIPTION

The synchronization of the generation of X rays and the readout of digital acquisition systems needs to be properly controlled, and is implemented through hardware and software.

Generator interfacing is normally done using a combination of asynchronous RS-232 ASCII commands and digital control signals (e.g. TTL, OPTO, RS422).

Often X-ray generators have established ASCII control sequences for setting variables, such as the kV and mA. New commands could be added as required.

It could be of benefit to integrate the generator console control functions into the digital display computer.

Obviously it is of importance to design the interface in a way that is the simplest and most intuitive for the technician and radiologist. Concepts readily accepted and loved by computer enthusiasts and systems designers may be unacceptable to the actual end user.

3. IMPORTANCE

Fundamental.

4. CLINICAL REQUIREMENTS

A very good understanding of clinical needs and methodologies.

5. COLLABORATORS

Clinicians, technicians and medical doctors.

6. CONTACTS

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Integration of Flat-panel Detectors to Magnetic Resonance Imaging

1. GOALS

The goals of the technology are to perform digital subtraction angiography and fluoroscopy at conventional image quality within the magnetic field of a magnetic resonance imager.

A major consideration is to make the system in such a way that the X-ray system does not interfere with the operation of the MRI and the MRI does not affect the operation of the X-ray system.

2. DESCRIPTION

Specialized flat-panel detectors and X-ray tubes are designed to operate in the magnetic field of the MRI, be immune to magnetic fields and the MRI's radio frequency interference (RFI) emission, and at the same time not generate RFI itself.

3. IMPORTANCE

This technology will extend the operation of MRI into the interventional arena without loss of image quality.

4. CLINICAL REQUIREMENTS

High-quality DSA (digital signal analyzer) and fluoroscopy for positioning and guidance of catheters and surgical tools.

5. ALTERNATIVES

The alternative is to try to improve the real-time application of MRI. However, this is largely impossible due to signal-to-noise considerations.

6. MATURITY AND RISK

Only prototypes have been demonstrated. Improvements in X-ray tube power handling to be used in magnetic fields are required, as well as incremental improvements in flat-panel imagers.
The heat loading of static anode tubes has to be increased and this may present difficulties.

7. AVAILABILITY

So far no major manufacturer has entered this field.

8. BREADTH OF APPLICATION

Not applicable to other sectors.

9. REFERENCES

Rowlands JA. 1999. "X-ray Imaging: Radiography, Fluoroscopy and Computed Tomography," in *Biomedical Uses of Radiation. Part A: Diagnostic Applications,* ed. W. Hendee (Weinheim: WILEY-VCH).

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Medical Imaging Technology

WG 2 - Final Working Group Report

COMPUTED TOMOGRAPHY
- Cardiac-gated Helical CT
- Flat-panel CT

Cardiac-gated Helical CT

1. GOALS

To eliminate cardiac motion on conventional single or multislice contrast-enhanced chest CT scans. This improves the visualization of proximal coronary artery calcification and intracardiac structures, and decreases transmitted cardiac motional blurring in the lung (right middle lobe and lingula). Potentially, this technique might allow CT assessment of coronary artery patency and myocardial perfusion. Currently it competes with electron beam CT, a technique that has been shown to have inadequate spatial and contrast resolution to replace diagnostic X-ray coronary angiography.

2. DESCRIPTION

Currently, electron beam CT can acquire cardiac images with 50 to 100 msec temporal resolution. However, this equipment has inferior spatial and contrast resolution compared to conventional helical CT scanners. Technical advances have increased the gantry rotation rate of current helical CT scanners to 0.5 seconds. Using a multislice acquisition and cardiac gating, a limited angle reconstruction technique can be targeted to either cardiac systole or diastole. Systolic and diastolic volumes and ejection fraction can then be calculated. Additionally, it may be possible to demonstrate the patency of distal coronary arteries in end diastolic images, potentially replacing diagnostic X-ray coronary angiography.

3. IMPORTANCE

The clinical impact of cardiac-gated CT would be large, since there is a large installed CT capacity in Canada, and this technique would improve image quality in the heart and lungs.

4. CLINICAL REQUIREMENTS

These techniques could be applied to any high-end helical CT scanner equipped with a power contrast injector.

5. ALTERNATIVES

Catheter X-ray angiography currently fills this role.

6. MATURITY AND RISK

Helical CT technology is established, but the gating technology and specialized reconstruction techniques need to be developed.

7. AVAILABILITY

Helical CT scanners are found in all Canadian urban centres.

8. BREADTH OF APPLICATION

This technology would improve cardiac and lung parenchymal diagnostic studies.

9. REFERENCES

The annual meeting proceedings of the Radiological Society of North America (RSNA) are a good source of data regarding the state of the art of cardiac-gated helical CT.

Flat-panel CT

1. GOALS

Current helical CT technology acquires four slices per rotation, leading to complete scanning of the chest or abdomen in 10 to 15 seconds. Large-area (30 to 40 cm along the z-axis) flat-panel detectors and cone-beam reconstruction techniques would allow these regions to be scanned in 0.5 to one second (one rotation). This would revolutionize body CT imaging, allowing near real-time visualization of complete body regions with isometric spatial resolution.

2. DESCRIPTION

Currently, multislice CT scanners acquire four slices simultaneously. The existing technology appears to be scalable to 16 or 32 simultaneous acquisitions. However, true volumetric CT should be possible using the flat-panel detectors currently developed for computed radiography. Modification of computed radiography technology to CT would result in the development of a revolutionary imaging technique that would be widely employed.

3. IMPORTANCE

The clinical impact of flat-panel volumetric CT would be large, as CT is a primary diagnostic instrument in Canada.

4. CLINICAL REQUIREMENTS

Clinical trials would be necessary to assess the clinical utility. This advance would likely allow CT to progress from an anatomic imaging tool to a functional and physiological imaging tool.

5. ALTERNATIVES

No current imaging modality provides this type of information.

6. MATURITY AND RISK

Basic research in X-ray detectors, reconstruction techniques and image display will be necessary to make this concept a reality.

7. AVAILABILITY

None at present.

8. BREADTH OF APPLICATION

This technology would improve all aspects of CT imaging.

9. REFERENCES

The annual meeting proceedings of the International Society for Optical Engineering (SPIE) and of the Institute of Electrical and Electronics Engineers (IEEE) are good sources of data regarding the state of development of flat-panel CT technology.

10. CONTACTS

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Medical Imaging Technology

WG 2 - Final Working Group Report

MAGNETIC RESONANCE IMAGING HARDWARE

- Gradient Coils with Higher Maximum Gradient Levels and Faster Slew Rates
- Specialized Radio Frequency Coils
- New MRI System for Specific Uses
- New Permanent Open-magnet MRI Systems for Specific Use in Neurosurgery
- Very High-field MRI Units (3 tesla or higher)

Gradient Coils with Higher Maximum Gradient Levels and Faster Slew Rates

1. GOALS

The performance goals of higher speed gradients are driven by MRI applications that require high speed imaging, including functional MRI, cardiac MRI and diffusion measurements. Conventional MRI gradients use slew rates of less than 20 mT/m/ms and maximum levels of 10 mT/m. High-speed imaging, in particular the single-shot echo planar imaging sequence, requires gradient slew rates greater than 100 mT/m/ms and maximum levels over 20 mT/m.

2. DESCRIPTION

Magnetic field gradients are an essential component of all magnetic resonance imaging scanners. They consist of three sets of conducting coils that produce linear variations in magnetic field along the x, y and z axes. In MRI pulse sequences, these gradients are rapidly pulsed on and off in synchrony with radio frequency pulses and data acquisition. The newer high-speed gradients differ from "conventional" gradients in that they use significantly more powerful gradient amplifiers and also require active air or water cooling mechanisms.

3. IMPORTANCE

The two most important applications of high-speed gradients, functional MRI and diffusion MRI, are playing an increasing role in research and diagnosis. Functional MRI enables the researcher to visualize brain activation. It is heavily used in brain mapping and in the investigation of brain behaviour in neurological diseases. In cardiac MRI, it is advantageous to obtain multiple images during the cardiac cycle. Diffusion imaging is playing an increasingly important role in the management of stroke patients.

4. CLINICAL REQUIREMENTS

Functional MRI and cardiac MRI require both high slew rates and high gradient levels. This is particularly important in high-field MRI for which the increased signal can be traded for higher bandwidth image data acquisition. Diffusion MRI requires mainly higher gradient levels.

At least two factors may limit the clinical applications of high field gradients. When the magnetic field varies by 60 T/s for longer than a few ms, nerve stimulation can be induced. Peripheral nerve stimulation can be induced with the fastest gradients available today. A second problem is acoustic noise, which is reaching unbearable levels with the newest gradients when these are operating at their maximum switching rates.

5. AVAILABILITY

The performance of the newest MR gradients is approaching the optimal levels required for the current applications.

6. COLLABORATORS

Gradient technology is largely developed by magnetic resonance technology manufacturers, including Magnex Scientific, Siemens Medical Systems, General Electric Medical Systems, Marconi Medical Systems and several others.

Dr. Brian Rutt's group at the Robarts Institute in London, Ontario, has an active research program in gradient design. The MR group at the Institute for Biodiagnostics has an active MR gradient design group.

7. COST-BENEFIT ANALYSIS

It is likely that within a few years most MR systems will be delivered with high-speed gradient systems.

8. IMPACT OF STANDARDS AND REGULATIONS

When the regulatory agencies settle upon limitations in gradient slew rates, gradient technology development will be affected.

9. REFERENCES

Recent unpublished work by Dr. Brian Rutt's group provides the best unclassified source on gradient design.

Specialized Radio Frequency Coils

1. GOALS

Clinicians are continually discovering new applications for MR imaging, and these new applications often require specialized RF coils to obtain the highest quality images in the shortest time.

2. DESCRIPTION

There are two main types of specialized RF coils. One type is for specific body parts and the other type is designed and built to be used during surgical procedures. The coils for specific body parts have been available for many years but they are in continuous evolution. A major step was the development of phased-array coils, since these have been developed for many applications. The evolution of these types of coils is such that head coils are now phased-array coils because this increases signal-to-noise and hence image quality and image clarity. Coils are made to study internal organs such as the prostate, for which the point of placement is the rectum, and the cervix, for which the point of placement is the vagina. The area for which there has yet to be a significant development is the human gastrointestinal tract, and this may not be realizable for a number of reasons, including geometry and movement.

There may be specific examples of circumstances in which coils such as those developed to study blood vessels may be employed. In all cases, the body-specific coil is a receive-only coil with RF transmission being performed by a body coil. The coils for use during surgical intervention face a different challenge in that the clinicians need high-quality images while retaining access for the surgical procedure. In the GE model, flexible coils were used with holes at the appropriate place for the surgical incision and the surgery. These coils suffered from lack of homogeneous field, and at many times the surgical access hole was in the inappropriate place. The system, which uses intermittent imaging during surgery, employs coils that can be removed very quickly following surgery to allow the surgeon access at the patient. The challenge is to develop coils that allow the required access, are quadrature and could be used for some real-time imaging.

3. IMPORTANCE

The requirements for body part-specific coils are really driven by the financial needs of the end user and to some extent by the patience level of the patient. The body part-specific coils are used to obtain high-quality images in the shortest possible time. If the technology is not available, MRI may lose some of its competitive advantages and other technologies may be employed. The interventional coils must respond to customer requirements. Surgeons will only change their methods slightly and so, if an interfering coil cannot be removed quickly, the surgeon will not use the technology. Surgeons are familiar with the image quality demanded by their radiology colleagues and they demand equal rights. Again, if the RF coil used in surgery results in inferior image quality or requires much longer time to acquire an image, then the surgeon will discard the technology.

4. CLINICAL REQUIREMENTS

The RF coils must provide excellent image quality in the shortest time possible. The RF field should be as uniform as possible over the volume of interest. For some applications, the coils must be disposable.

5. MATURITY AND RISK

There are a large number of specific body part coils available from all the major MRI vendors, and there is also a significant number of specialized coils available from companies who make customized coils.

The main capability sought by users is the ability to obtain higher quality images in a shorter time. In using MRI in the operating room, the challenge is to increase signal-to-noise and to increase image uniformity over the volume of interest. There is also the challenge of making the RF coil invisible to the surgeon, at least for the surgical intervention.

At some point, the limits of physics will be reached, and this is the main risk of this technology. However, there are a number of parameters that can be manipulated, and new, better coils for specific applications will be developed.

6. AVAILABILITY

As stated above, these coils can be obtained from all the major MRI manufacturers, as well as from a number of specialty companies. These special coils are relatively expensive and are a good source of revenue for the successful companies. However, in comparison with the cost of an MRI system, the cost of coils is relatively low.

7. BREADTH OF APPLICATION

There are some players in Canada who develop specialty coils and who sell either to major firms or to end users. These are often associated with a research organization at which the need for the specialty coil was first learned.

8. COLLABORATORS

The National Research Council (NRC) has developed a number of coils over the years and has the necessary expertise to design and build the coils. Recently, researchers at the NRC developed a coil for breast imaging that doubled the signal-to-noise ratio, which would provide benefits commercially as well as to the patient.

9. COST-BENEFIT ANALYSIS

If one can develop a coil that is in demand, then it is a reasonable revenue generator, since the cost of production is generally low relative to the sale price.

10. IMPACT OF STANDARDS AND REGULATIONS

New coils need to be certified through the Health Protection Branch (Canada), the Federal Drug Administration (U.S.), and CE (Europe), but this is generally straightforward.

New MRI System for Specific Uses

1. GOALS

The technology is driven to a large extent by customer demands. MRI continues to expand its applications to diagnosing different diseases. In the early days of MRI in the United States, 80 percent of MRI examinations were for the brain. Today it is less than 35 percent, but there are more brain MRI scans being performed now than ever before. The original MRI units tended to be all-purpose machines that were adequate for all body parts but not ideal for all. Today equipment tends to be specialized for a particular application, such as for cardiac MRI. Most of the major MRI manufacturers will sell a system specialized in, if not dedicated to, cardiac imaging. The reason is that there is such a demand for imaging of the heart that it is economical to produce an instrument that concentrates on this part of the body. This means that coils such as gradient and RF can be optimized for this area of the body. Surgery is another area for which specific equipment can be developed to satisfy only this need.

2. DESCRIPTION

The equipment is an MRI instrument that has been developed for a specific application, for either a body part or a clinical procedure. Most of the system will be designed for this particular application, but whenever possible the manufacturer will use core technology. Thus, the core software for most equipment is the same, with specific overlays being added to take into account the specific application. There is a move to develop MRI systems for groups other than radiologists, at least as the first point of contact. There has been considerable effort to develop MRI equipment for extremities, with orthopedic surgeons being the first contact persons. The most successful will be those who develop a system that will fit into a clinician's office. An extremities system would be extremely useful for a rheumatologist, for example, provided that one of the clinician group's offices contained the MRI. It is a similar scenario to visiting the sports medicine clinic where an X-ray unit is available. The MRI must be very compact and user-friendly, with a means of transmitting images to radiologists that is essentially on-line. Head-only MRI systems have been developed, and these employ compact magnets with special gradients that allow very high slew rates. The major technology advancements are in the magnet, the gradients and the RF coils, as well as in some software overlays. It is an area that will expand.

3. IMPORTANCE

MRI has developed into a very powerful diagnostic tool with an ever-increasing number of applications being developed. More and more clinicians from different specialities are demanding MRI as the major diagnostic tool. However, relative to many other techniques, MRI is very insensitive. Therefore, an MRI machine that can be used for many applications is, from an economic standpoint, difficult if not impossible to construct. The reimbursement rate for MR images continues to decline, which means that the equipment must become more and more efficient, thus the increased interest in MRI equipment for specialized applications.

MRI has become such a desired technique that clinicians feel obligated to prescribe its use or face the potential of legal liability. This, in many ways, is in contrast to the economic orientation, which aims to do more for less. The only way to do more for less is to use dedicated equipment that is very efficient. It is, in fact, the increased demand that is making the development and utilization of dedicated equipment economically feasible.

4. CLINICAL REQUIREMENTS

The equipment must be very efficient and provide a high throughput of patients with very high-quality images.

5. MATURITY AND RISK

There are more and more systems with dedicated applications entering the market place. Not all have been successful, but some may eventually become so.

6. AVAILABILITY

The major MRI manufacturers are involved in some of these developments, but it is an area in which smaller companies with a particular target market are having some success. These specialized systems are generally less expensive than the equipment found in radiology departments around the world.

7. BREADTH OF APPLICATION

At present, Canada has one company that could be placed in this area, producing an MRI system for the operating room, and also a head-only system. Specific-use MRI systems represent a niche market in which a Canadian company with good technology could prosper.

8. COLLABORATORS

The above-mentioned company is an NRC spin-off and so the technology is available within the NRC. There a number of research organizations in Canada that have the technology to be able to enter this market.

9. COST-BENEFIT ANALYSIS

As alluded to above, this is a market that will expand. It is also an area in which relatively small players have the potential to be successful provided they have unique technology and have applied this technology to an area that is truly a niche area in the medical field.

New Permanent Open-magnet MRI Systems for Specific Use in Neurosurgery

1. GOALS

The proposed permanent magnet neuroimaging system would allow real-time interventional neurosurgery. The system would drastically reduce the time needed to carry out many procedures. The system may reduce times as much as 30 to 50 percent over conventional techniques.

In discussions with staff of a large Canadian teaching hospital's department of neurosurgery, it was revealed that of 2600 intercranial operations carried out in the previous 12 months, 1000 would have benefitted from the technology.

The shortening of the operation and the increase in detail viewed during the operations would have a positive effect on patient recovery. It would also allow surgeons to carry out many procedures on a more timely basis, reducing costs all-around. The price point would be comparable to the high-end movable CT systems designed for interoperative neural imaging.

2. DESCRIPTION

This technology is used for the design and testing of non-conventional system configurations for specific uses. A small permanent magnet used in conjunction with new interventional RF coils allows real-time MRI viewing during neurosurgery. The magnet design and coil development are very forward-looking and have applications in other low- to mid-field magnet systems in the open configuration.

The design proposed here is a small, movable U-shaped magnet that can be positioned in a conventional surgical suite. The RF coil is of a surface design and is directly gradient-driven. The system has a high level of self-shielding, and the magnet is passive with the electronics all contained in the RF/gradient coil, which also serves as the head frame. The reconstruction system is rapid, using the newest PC-based computer technology.

3. IMPORTANCE

A technology of this type reflects new thinking and is not currently under development anywhere in the world. The system would cut costs in Canadian health care and be a very desirable export product for a Canadian company.

The technology is a quantum leap forward from the use of CT coupled with conventional optical neurosurgery.

4. CLINICAL REQUIREMENTS

The exacting standards set by the physicians in the world of neurosurgery.

5. ALTERNATIVES

Interoperative systems:

- the interoperative MRI system from IMRIS in Winnipeg;
- portable CT systems from the major manufacturers of medical imaging devices; and
- the conventional C-shaped open MRI systems from Marconi, Siemens and Millennium Technology Inc.

6. MATURITY AND RISK

MRI has the capability to carry out real-time neuroimaging, but the magnet configurations for this type of system do not exist. The system is five to seven years from market and 10 years from significant acceptance in the industry.

The schedule of development would look like this: two to three years for the RF/gradient coil, three to four for the magnet and configuration, four to five for preclinical testing, five to six for clinical testing and approvals, and seven to ten for marketing.

The main risk is technological; the RF/gradient system may take much longer to develop than the two to four years anticipated.

7. AVAILABILITY

Not available as an interventional system. The closest approximation would be an interoperative system from IMRIS. The cost of the interoperative system is high, as it comprises the cost of a superconducting MRI system plus the modifications that allow the magnet to move during the neurosurgery.

8. BREADTH OF APPLICATION

The technology developed in this application would be available on a much shorter time line for less invasive types of interventional surgery. The practice of interventional surgery is in its infancy and will become very well developed in the next 10 to 15 years.

9. COLLABORATORS

The development of the system would involve one or more major teaching hospitals in Western Canada. It is also possible that, although the expertise in manufacturing is predominantly in the United States, there are Canadian companies that have evolved to the point of being able to assist in the development.

10. COST-BENEFIT ANALYSIS

The equipment development costs will be in the $5–7.5 million level over four to five years. The annual revenues for selling 25 systems per years would be $42 million per year in revenues.

In terms of job creation, there would be five jobs at the PhD level, seven to ten jobs at the MSc level, 10 in-house tech jobs per year, and four to five contract jobs at the PhD/MD level. This does not include the support or administration functions, nor the spin-offs such as hardware manufacture and machining.

11. IMPACT OF STANDARDS/REGULATIONS

None.

12. REFERENCES

In-house work only.

13. CONTACTS

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Very High-field MRI Units (3 tesla or higher)

1. GOALS

At the present time, the customers for this equipment are clinical researchers who require information on the brain from techniques including functional MRI and MR spectroscopy. As the technology develops, it will become more and more driven by clinician requirements.

The economic aspects of the technology are important since MRI within a hospital, particularly in the United States, is seen as a revenue generator. If this new technology is to expand significantly, then it must move into the clinical diagnostic suite and be used for routine examinations. The cost will become very important since it will be compared with the top-of-the-line 1.5-tesla systems currently in all major hospitals in North America and Europe. The cost of a 3-tesla whole body system is more than US$3 million. The cost for the other systems is even higher. Most of the ultra-high systems, more than 5 tesla, have been integrated by the researcher group, who bought a magnet from Magnex and electronics from companies such as Varian and Bruker. An interesting development is the apparent involvement of Siemens in the 7-tesla system at the Massachusetts General Hospital in Boston.

2. DESCRIPTION

The diagnostic MRI market is currently dominated by equipment equipped with 1.5-tesla magnets. There are approximately sixty 3-tesla and five 4- (or 4.7-) tesla instruments worldwide. To this can be added, one 8-tesla and one 7-tesla instrument, with another two 7-tesla and even two 9.4-tesla magnets in production. These very-high field systems have been used primarily for research, particularly for functional imaging of the brain. It is believed that over the next four years, the number of systems produced based on 3-tesla magnets will increase to at least 100 per year. At this point, the systems will primarily be used for clinical diagnosis. The research customers will concentrate on the even higher field magnets.

3. IMPORTANCE

Currently, the MRI and clinical research community are driving the development of very high field MRI. The luminary diagnostic imaging sites are in the process of replacing their upper-end 1.5-tesla systems with 3- or 4-tesla systems, and this trend will continue.

4. CLINICAL REQUIREMENTS

These new higher-field systems must supply significantly more diagnostic information in a shorter time than what is already obtained at 1.5 tesla. This relates to 3- and 4-tesla systems. Techniques such as functional MRI must be shown to have definite clinical value, and the functional images at 3 or 4 tesla must provide more information than at 1.5 tesla.

5. ALTERNATIVES

The major competitor is, in fact, 1.5-tesla MRI. Techniques such as PET (positron emission tomography) can provide functional brain data, but not on the scale that very high field MRI can.

6. MATURITY AND RISK

The technology as applied to the brain is providing invaluable information on brain activation. The use of very high field magnets to improve diagnostic information from anatomical imaging is being developed.

The MRI magnets will only show, and will only need to show, marginal increments over the next several years while the rest of the technology catches up. As stated above, functional MRI and MRS must become truly clinical to the same level as anatomical imaging. Imaging of other parts of the body must be developed. The heart would be an excellent candidate for very high field MRI imaging but there a number of challenges that need to be overcome. The area of MR angiography at very high field could also be an exciting technique and again many challenges will need to be overcome.

The risks are similar to those that were present several years ago for 1.5-tesla systems

7. AVAILABILITY

GE, Siemens and Marconi all offer systems with 3-tesla whole body magnets. Varian and Bruker offer anything from 3-tesla to 9.4-tesla systems. These are truly research systems and their sophistication with respect to clinical software is less than that of the systems of the major clinical scanner providers. They are very flexible and ideal for the research community.

8. BREADTH OF APPLICATION

In Canada, there are several 3-tesla and 4-tesla systems located across the country, and the number should expand. Several Canadian research groups are involved in developing peripheral equipment for work with these systems. IMRIS, a Canadian company, markets and sells a head-only system based on Marconi electronics. The product has undergone some major modifications and will appear as a 4-tesla head-only system concentrating particularly on functional MRI in the future.

9. COLLABORATORS

The NRC has been at the forefront of developing very high field MRI applications and will continue to be so. There are a number of university and associated research institutions that are involved in developing the technology and peripherals.

10. IMPACT OF STANDARDS AND REGULATIONS

GE has U.S. Food and Drug Administration approval for its 3-tesla system, and Siemens will follow closely behind. MRI units with static fields up to 4.1 tesla have been deemed safe by the FDA, provided the other safety issues such as SAR (specific absorption rate), dB/dt and acoustic noise are within prescribed limits.

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Medical Imaging Technology

WG 2 - Final Working Group Report

IMAGE-GUIDED SURGERY

- Software Packages
- Magnets Specialized for Surgical Procedures
- Operating Room Suites Designed for Intraoperative MRI

Software Packages

There are four principal areas of software packages for image-guided surgery that are treated in this section, referred to hereafter according to their assigned number (e.g. *2.3* refers to package three, *2.4* to package four, etc.):

1. Superposition of images from navigation devices into a surgical microscope.
2. Image fusion and image morphing to use high-resolution images to improve low-resolution data.
3. Software to follow brain tissue recovery after surgery.
4. Real-time viewing of procedures and ability to remotely monitor procedures.

1. GOALS

All of these software packages are driven by the customer's need to have better and more accurate pictures more quickly (in most cases, the customer is a surgeon). The pictures must also arrive in a very user-friendly fashion and not unduly interfere with the physician's normal method.

The cost to develop these packages varies, but each one will require several person years of software development, testing and trials to verify that what is provided is what the surgeon needs. Once the package is developed, it will be sold for a reasonable amount of money.

2. DESCRIPTION

2.1 Superposition of Images from Navigation Devices into Surgical Microscope

The surgical microscope is used by the surgeon to attain a very good view of the target, or the tissue on the way to the target, with a minimum incision into the body. The microscope is an extremely important adjunct to the neurosurgeon because of the sensitivity of brain tissue, and the surgeon must have minimal impact on normal tissue when locating and removing the target. The microscope does not help the surgeon locate the target. This is performed using a surgical navigation device.

The problem has been that the surgeon looks through the microscope directly into the operating field but has to look at another computer screen to follow surgical navigation. This method is inefficient and gives surgeons kinks in the neck. The obvious answer is to project the images from the navigational device into the microscope. The difficulty in neurosurgery is that the brain shifts as the surgery proceeds. As a result, the navigational images lose accuracy with time. It is also important that there be a direct and robust correlation between the two technologies and that both sets of views be from the same position. The technology to project the images from the navigation device into the microscope is in the process of being developed. This project does not overcome the problem of brain shift, which emphasizes the need for intraoperative imaging.

2.2 Image Fusion and Image Morphing to Use High-resolution Images to Improve Low-resolution Data

The preceding discussion in some ways leads into this particular subject because rapid image updates are needed to keep navigational devices accurate. The best technique for anatomical imaging of the brain in particular, and the body in general, is MRI. Another excellent technique is CT. CT is even more precise than MRI. The first fusion techniques in image-guided surgery were in fact intended to combine the precision of CT with the tissue-contrast characteristics of MRI.

The types of algorithms that can be used include linear and non-linear. Linear algorithms are more precise but cannot take into account some distortions found in MRI. This can lead to less accurate results. The other image data that need to be fused include functional MRI data with anatomical MRI (which is straightforward), and PET or SPECT data with MRI. All of this data can have an impact on the surgery. The algorithms to fuse one set of image data with another exist and appear to be reasonably useful. Further algorithm development needs to be done, and the process must be sped up for use with intraoperative imaging techniques. The development of image fusion techniques to improve a poor image with previous high-resolution images represents a higher degree of difficulty.

2.3 Software to Follow Brain Tissue Recovery After Surgery

This is a software package that will predict how the brain recovers following surgery for a lesion. In some respects, this technology is part of a larger area of study trying to understand how an individual's brain correlates with the "average brain."

2.4 Real-time Viewing of Procedures and Ability to Remotely Monitor Procedures

The real-time viewing is essentially available, as is the ability to remotely monitor what is occurring in surgery. The latter is covered by PACS, which are already in many hospitals, and are in the process of being implemented where they do not currently exist. All the major imaging companies can control the equipment from home base. For example, the Canadian company IMRIS has a system in Calgary, and this well-established technology could be controlled and manipulated from Winnipeg.

3. IMPORTANCE

In many ways, these software packages represent an important area of medical imaging technology development. This is in many ways a fairly important area. There is the sense that more could be made from the available image data to help a patient recover from a malady requiring surgical intervention. The techniques developed in this area are subjected to hard scrutiny by bodies such as the U.S. Food and Drug Administration, but it may well be that in the future techniques will only be approved when companies demonstrate that software packages are available that permit maximum results from the technology.

The technology is important to the patient and physician, and to health care in general. It is well known in medicine that if a complex procedure is made easier, then outcome is improved, hospital stay is reduced and productivity is increased. These software packages will make surgical procedures easier and will have a positive impact on health care dollar expenditure.

4. CLINICAL REQUIREMENTS

The software packages must work and must be accepted by surgeons as an adjunct to their surgical procedure.

To be successful, the technology described in 2.1 must be accepted by surgeons as being very accurate and must allow them to perform the procedure with complete confidence. There are many surgeons who now turn off the navigational device when using the microscope, since it is a pain in the neck (literally and figuratively) to move the eyes from the microscope to the computer screen of the navigational device.

There is no doubt that intraoperative imaging can have a major impact on patient outcome following surgery. The software packages that would allow low-resolution images to be improved by previously obtained high-resolution images must be accepted by the surgeons.

5. ALTERNATIVES

Ultrasound is another imaging technique. The combination of ultrasound and MRI could be a very powerful one, with the low-resolution technology being provided by ultrasound. There are groups that use low-field, and therefore low-resolution, MRI in the operating room and attempt to combine the low-resolution images obtained intraoperatively with high-resolution pre-operation ones. Ultrasound combined with some high-resolution MRI is more feasible, both medically and economically.

6. MATURITY AND RISK

6.1 What the Technology can do Today

There is technology available in the marketplace that will physically allow one to project images into the microscope (software package 1). The major image-guided surgery companies all provide this software for use with most commercial top-of-the-line microscopes. Surgeons are not using it as an everyday feature.

All major companies selling image-guided surgery equipment provide an image fusion package to fuse MRI and CT data (software package 2). Most also allow the fusing of PET and SPECT data. There are variations from company to company and the practice is still not completely accepted by the surgeons.

Again, software is available that will provide an estimate of how post-surgery brain recovery may occur (software package 3), but a significant amount of testing still needs to be performed. The clinical applications of this software are several years from reality.

6.2 Incremental Capabilities Required to Produce the Products Required for the Next 4 to 10 Years

The major challenge, at least for application of software package 1 to brain surgery, is to link the intraoperative imaging so that the surgeon is confident that the image in the microscope corresponds with reality. There will also need to be improved visualization of the navigational image within the microscope.

The technology related to software package 2 will be the most difficult to develop, since it is very difficult to make a silk purse from a sow's ear, which is essentially what the objective amounts to. Surgery, particularly in the brain, results in tissue movement, and it is often the tissue close to where the movement has occurred that we need to visualize accurately. For example, as a large lesion is being resected in the brain, the normal tissue can often relax towards or away from the surgeon. It is important for the surgeon to know precisely which is occurring if intraoperative imaging is to be useful. Also, the amount of tumor left when the surgeon believes that the lesion has been completely resected is often fairly small, and may not be detected by low-resolution imaging, and fusion with high-resolution images will not help. There will be a number of challenges, serious challenges, but this should not deter one from trying since an ultrasound in the operating room is much cheaper and easier than an MRI.

The next step is for serial imaging to be performed so that one can monitor the way the brain relaxes following resection (software package 3) and observe the correspondence between software estimation and reality. The software will no doubt need to be modified as a consequence of this experimental evaluation.

Software packages enabling real-time surgical viewing and remote monitoring will become more and more rapid.

6.3 Risks Associated with Obtaining Incremental Capabilities

There are fairly minimal risks associated with software package 1.

As discussed above, software package 2 is the most challenging of the four packages because the tissue around the most critical area, the resection area, will be moving.

There simply may not be an average way the brain relaxes following surgery.

7. AVAILABILITY

Image-guided surgery companies such as BrainLab and Sofamor Danek provide a software package similar to that described in 2.1 with their products and at least the MRI/CT fusion software. There are a number of academic institutions involved in this work as well. A software package such as that described in 2.3 may not yet be available, but there are companies involved in developing this because of its significant potential. It is possible that knowledge of how the brain relaxes following surgery will have significant ramifications for understanding how the brain functions and how the brain can be repaired.

8. BREADTH OF APPLICATION

8.1

Software package 1 is linked to the medical industry and there seems to be little activity in this area in Canada.

8.2

Software package 2 could have a much broader application because it concerns image fusion and could be any type of digital image. It could be related to different images obtained for industrial applications, which could be of interest to the oil industry and potentially even the espionage industry. In the medical field in Canada, it is of significant importance to optical imaging companies such as Life Imaging in London. There could be an interest on the part of a software company such as Cedara, as well as an intraoperative MRI company such as IMRIS.

8.3

Software package 3 does not enjoy a very broad application and there is little activity in Canada on this front.

9. COLLABORATORS

A group in Montreal located near McGill, as well as those in London, Ontario, located near the Robarts Research Institute. There is a very large image analysis group in Toronto, as well as significant research in ultrasound imaging.

10. COST-BENEFIT ANALYSIS

Globally, there are a number of commercial enterprises interested in this technology. It has the potential to be profitable. Existing software and image analysis organizations should be approached and assisted in this area.

11. IMPACT OF STANDARDS AND REGULATIONS

The U.S. Food and Drug Administration is always a significant hurdle for any medical device, and this will not be an exception. This type of software may in the future have an impact on some medical device requirements.

Magnets Specialized for Surgical Procedures

1. DESCRIPTION

This technology is best described in terms of the double-donut magnet designed and produced by General Electric. The system essentially consists of two magnets separated by about 50 cm that interfere constructively in the centre to produce a homogeneous magnetic field of sufficient field-of-view for most MRI studies. The two magnets are annular and the patient enters the magnet in a similar fashion to most other MRI magnets. Surgeons can then enter in between the two magnets perpendicular to the patient bed and the patient. The area of surgery is placed in the centre of the two magnets. The surgeon can then operate and in principle follow the operation in real time using MRI. The strength of the magnetic field in the imaging area is 0.5 tesla, which is sufficient to provide adequate images. A big advantage of this system is that patients can be operated on and imaged while sitting up. There are several systems in the world and most have been used for neurosurgical procedures. Although neurosurgical procedures are most in need of MRI guidance, this particular system is probably better suited for other parts of the body.

Another system intended for surgery has been designed and built by an Israeli company called Odin. The magnet operates at 0.12 tesla and is placed under the operating table. When required for imaging, the magnet is raised and surrounds the head. After imaging it is then retracted and the surgeon can continue with surgery without any encumbrance. This system has also been designed specifically for neurosurgery.

There are several other systems in which relatively standard magnets have been modified for surgical procedures. This includes a system developed by the Canadian company, IMRIS, that moves a 1.5-tesla magnet in and out of the operating field. Siemens and Philips use 1.5-tesla magnets with special tables that move the patient in and out of the magnet when imaging is required.

The open magnets have also been adapted to monitor surgery. The new higher-field open magnets appear attractive for surgical procedures since in principle there should be space for access to the patient. The problem is that the higher the field the larger the magnet; therefore access to the patient at the centre of the magnet becomes difficult.

2. IMPORTANCE

MRI has been on a sharp utilization curve since its implementation in the early1980s. It is now the imaging technique of choice for many areas of the body, and has had a major impact on physicians' ability to diagnose disease. The obvious next step is to use this technology's power during surgical procedures. MRI is often better than the human eye at distinguishing between a lesion and normal tissue, and has the power to provide information on blood flow and blood perfusion. These can all be critical factors to monitor during a surgical procedure.

3. CLINICAL REQUIREMENTS

The magnets must be a critical component of the MRI equipment that will provide the surgeon images during the procedure. The magnet should not interfere with the surgeon's normal mode of operation and should not increase operating time. The magnets must be designed such that the anesthetists can see the patient at all times and can monitor the patient's vital signs.

4. ALTERNATIVES

There are other technologies that have been introduced or that are being introduced into the operating room to provide images to the surgeon. CT was introduced into the operating room more than 20 years ago, but it has never gained universal acceptance. X-rays in various forms have been used in the operating room, but their use is decreasing.

Ultrasound provides a very interesting alternative since it is inexpensive and can be used quickly and with some precision. The difficulty is that image quality is inferior and that it is still fairly operator-dependent. The new Doppler ultrasound techniques, which can use vessels as a landmark, are an exciting development in the use of imaging in the operating room.

5. MATURITY AND RISK

The technology can provide MR images in the operating room that are useful for guiding the surgeon, and for determining how much of the lesion has been resected and whether surgery has caused any complications.

The 1.5-tesla magnets used by IMRIS, Siemens and Philips provide high-quality images. The magnets need to be shorter and to have a larger diameter so that the surgeon can reach in and operate on the patient during imaging. Alternatively, the open magnets must become higher field and remain very compact so that surgeons can operate comfortably on the patient.

The problem at the moment is the laws of physics, which tend to require large magnets for large fields. The requirements of MRI-guided surgery will probably be best solved by combining MRI, surgeon-controlled surgical arms and very powerful image-guided surgical software packages.

6. AVAILABILITY

The magnet can be obtained from all the major MRI producers, as well as from IMRIS and Odin. The Odin system costs about US$800 000, whereas the 1.5-tesla system, as well as the GE double-donut, cost between US$2–3 million. The Canadian company, IMRIS, will provide a system in the near future that will be the equivalent of the surgeon's microscope and will cost around US$1 million.

7. COLLABORATORS

The National Research Council has been very much involved in the development of the Canadian equipment. There has been considerable work performed in Toronto using an open magnet turned 90 degrees from normal orientation. Although the magnet itself may not become commercial, much of the surrounding technology could have an impact. The open magnet developed by Millennium Technology from Vancouver may also be used in the operating room.

8. COST-BENEFIT ANALYSIS

The GE double-donut technology has been available for about five years, yet only about 20 systems have been sold worldwide. A major reason is cost-benefit. The system is very expensive and in the U.S. there is little chance of recovering the costs. Diagnostic MRI equipment will scan 15-20 patients daily without difficulty and, even at $700 per patient, the initial capital outlay can be recovered. In an operating room, there will probably only be three or four reimbursable scans per day, hence the hospital cannot recover the outlay. The advent of the moveable MRI scanners, such as those from IMRIS, which can be used in both the operating room and diagnostic suite, will make it more economically justifiable to use the system.

9. IMPACT OF STANDARDS AND REGULATIONS

The GE double-donut has been approved by the U.S. Food and Drug Administration, an approval made more difficult because this technology involves surgeons their instruments being in the magnetic field at all times.

Operating Room Suites Designed for Intraoperative MRI

1. GOALS

Many surgeons, particularly neurosurgeons at this stage, desire to have MRI imaging available during the surgical procedure. There have been several solutions proposed and implemented to satisfy this demand. They can be classified into three categories: operate in a magnet, move the patient into the magnet when imaging is required, and move the magnet around the patient when imaging is required. Each provides challenges with respect to the operating room suite. The need to provide this suite is driven by the customer, who requires the MRI under one of these conditions but needs help in developing the suite.

The goal is to very quickly provide a turnkey MRI in the operating room. If the hospital is performing major renovations anyway, then the time element is less important. If it is the renovation of an existing suite, then time is extremely important, particularly in the U.S., since operating suites produce revenue for the hospital.

The cost of the suite will be approximately US$1 million, and the equipment must be modular so that it can be installed quickly. The end user, most likely a hospital, will be required to provide a bare shell of sufficient size to permit the installation of the MR equipment in both a diagnostic and an operating suite.

2. DESCRIPTION

It is necessary to provide to the hospital a turnkey renovation that includes an MRI unit. The type of system will have a major impact on the building renovations. The system with which the surgeon operates on the patient in the magnet is relatively straightforward and will most likely be produced by GE, so it will not be discussed here any further. The scenarios involving moving the patient and moving the magnet offer, in some ways, similar challenges and, in other ways, very different challenges. In both scenarios, the system would be installed such that both operating room and diagnostic patients could be scanned. In the move-the-patient scenario, a very complex table is used to transfer the patient across the room, from where the operation is taking place into the magnet and back. When surgery is completed for the day, the MRI can be used for diagnostic patients. In the move-the-magnet scenario, the magnet moves from its docking station to the patient when required for imaging and then back to the docking station. When in the docking station, diagnostic patients can be brought to the magnet and scanned.

3. IMPORTANCE

The idea of placing an MRI in the operating theatre as an adjunct to surgery is in many respects still in the development stage, and the technology of providing a turnkey solution responds to a need expressed by potential customers. It removes a serious concern for the hospital administration. If the turnkey solution is not viable, then the introduction of MR units into the operating suite will be slowed down.

4. CLINICAL REQUIREMENTS

The major clinical requirement is to effectively keep the surgical component of the installation sterile but still allow outpatients to be imaged in the diagnostic suite. This will involve not only the magnet movement but also patient traffic flow. Outpatients must not enter the surgical section, and so the site has to be well planned.

5. MATURITY AND RISK

The design process for both the move-the-magnet scenario and the patient-to-the-magnet scenario is quite advanced. The first examples of both were expected to appear in the first part of 2001.

It is unknown how risky it is to enter this field. The answer to this question will be known once the first systems are evaluated. It will also depend significantly on the complementary technology the surgeon will desire to add. Navigation equipment is one such extra technology, and there is only a limited amount of space around the patient.

The risks are fairly minimal unless the additional technology is not MR-compatible or is relatively large.

6. AVAILABILITY

The most advanced patient-to-the-magnet scenario is being developed by Siemens, which has invested heavily in the project. The magnet movement development is being done by IMRIS, the Canadian company, in collaboration with its partner BrainLab from Munich, Germany. The estimated cost of the latter is less than US$1 million.

7. BREADTH OF APPLICATION

Once the first systems are tested, there may be an opportunity for what are essentially hospital construction firms with good understanding of MRI installation to become subcontractors.

8. IMPACT OF STANDARDS AND REGULATIONS

There should be minimal impact with respect to the normal regulatory bodies such as the U.S. Food and Drug Administration, but building specifications will be a consideration.

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Medical Imaging Technology

WG 2 - Final Working Group Report

NUCLEAR IMAGING

- Software
- Hardware
- Clinical Radiopharmaceutical Agents

Software

1. GOALS

The goal of nuclear imaging is to visualize in 3-D the distribution of radioactive tracer in the human body. This technology has long been recognized as a powerful diagnostic tool to investigate organ functions and changes in metabolism caused by disease processes. Currently, the majority of clinical studies display only stationary activity distributions and the analysis of the resulting images is mainly qualitative. It is believed, however, that absolute quantitation of the data would yield greatly enhanced diagnostic accuracy of the tests. Further improvements could be achieved by using fully quantitative and/or dynamic functional imaging.

2. DESCRIPTION

Nuclear imaging certainly cannot exist without computers. Over the years, sophisticated software has been developed and is not only used to acquire, process, display and analyze patient studies, but also to perform various tasks related to camera quality control. The role of data acquisition computers is to control camera movements, operation of acquisition electronics, and flow and storage of the data. All these functions have to be performed quickly in order not to decrease the number of recorded photons and not to prolong the studies. Gated-cardiac and dynamic studies, dual isotope or simultaneous emission-transmission acquisitions and scatter corrections may require collection and storage of several additional sets of multidimensional data. These huge data sets need to be processed, and this task is often done on a separate processing computer. Images are reconstructed and filtered, and various corrections may be applied at this point (such as attenuation, scatter and other). Further data processing, such as smoothing, reorientation, multislice display, volume of surface rendering for 3-D display, and parametric display, are aiming at optimal data presentation for visual or quantitative analysis. This final step may include 2-D or 3-D segmentations, drawing different profiles, curve plotting, performing kinetic model calculations, and analysis of other parameters.

3. IMPORTANCE

Future development of nuclear imaging must certainly involve substantial advances in all these areas. In the past, PET (positron emission tomography) and SPECT (single photon emission tomography) have evolved following slightly different paths, and some corrections or reconstruction techniques are more appropriate for one modality than for the other. The advent of hybrid systems and other multimodality cameras such as built-in CT (computed tomography) scanners has prompted revision of this approach and development of new hybrid methods. As such systems may prove to be more versatile, powerful and cost-effective, further work in this area should be encouraged. Additionally, as new systems that replace lead collimator with electronic collimation and coincidence detection of Compton scattered photons are being proposed, appropriate reconstruction programs will need to be developed. This is because these cameras have a completely different design and will require very complex 3-D data processing as well as extensive computer storage.

4. CLINICAL REQUIREMENTS

The role of any nuclear imaging is to allow physicians to obtain functional information from the living human body by measuring the distribution of radiation at various locations around the patient. This is best done by performing a tomographic study, in which 3-D images of activity distribution are reconstructed from a series of planar 2-D projections (SPECT). Although planar nuclear medicine studies, in which the data is acquired at a single camera position, still constitute about 50 percent of the procedures performed in an average nuclear medicine department, tomographic 3-D images certainly provide more diagnostic information and, in the future, one can see tomographic studies even completely replacing planar scans. This can happen only when the appropriate scanning equipment is available, such as tomographic whole body scanners with the appropriate image reconstruction software. In PET, acquisitions are often performed in 3-D mode, but still the data are rebinned into 2-D slices in order to speed up image reconstruction. It is hoped that improvements in both computer software and hardware will allow full 3-D image reconstructions.

Basic clinical requirements for nuclear imaging software may be summarized as follows:

- short scanning time for the patient (fast data acquisition, transfer and storage);
- short data processing and image reconstruction time (fast computers, efficient algorithms);
- large detector scanning area, ideally covering whole patient body (computers dealing with large data sets);
- quantitatively accurate static and dynamic images (sophisticated correction methods using efficient algorithms); and
- accurate, reliable and automatic (with possibility of user intervention) data and/or images analysis methods (fast 3-D computer graphics, data segmentation and processing, computer-aided diagnosis).

5. ALTERNATIVES

Other imaging techniques use X-rays (CT), magnetic fields (MRI - magnetic resonance imaging), sound waves (ultrasound), or electric and magnetic signals (EEG and MEG -electroencephalography and magnetoencephalography). Each technique uses a different physical phenomenon and therefore generates different information. The advantages of nuclear imaging are its extremely high sensitivity (nanomolar concentrations) and ability to image the functions of an organ.

6. MATURITY AND RISK

The principle of operation of a ring PET system is that the system provides tomographic projection data without camera movement, but even then the data are often acquired and/or reconstructed in a 2-D or only semi-3-D mode (Fourier rebinning). Fully 3-D reconstructions will require further development of iterative image reconstruction techniques. In SPECT 3-D, imaging corresponds to cone-beam or fan-beam data acquisition and reconstruction and currently has only limited clinical use. Larger computer memories, improved computational speed, better calculation accuracy, faster algorithm with more stable convergence properties, and implementation of new optimization methods (in particular, the use of regularizers) are only some of the issues that need to be investigated.

Furthermore, standard clinical evaluation of images primarily uses qualitative visual analysis of static activity distributions, since exact quantitative information is usually unavailable (with the exception of some research centres). Development of practical quantitative methods for PET and SPECT may significantly improve the diagnostic potential of these techniques. This step, however, requires substantial improvement of the attenuation and scatter correction techniques. Transmission scanning systems, using radioactive sources or low-grade CT scanners, are already available for many cameras (PET, SPECT or hybrid systems), but the accuracy of the attenuation maps and their implementation into the attenuation correction methods still require a lot of work.
An even less advanced situation exists with scatter correction, which in an ideal case should include density distribution information from the attenuation map. Currently available 2-D scatter-correction methods, which use slice-by-slice reconstructions, certainly are not adequate because photons may scatter in any direction, not only in a single plane. Iterative resolution recovery methods (in SPECT) and partial volume effect (in all systems) need to be addressed in fully quantitative imaging. Ideally, all these corrections should be implemented using a unified approach, which may require huge computer memory and substantial improvement in computer speed.

Practical and clinically viable normalization methods will have to be developed in order to obtain absolute quantitation of data. Such absolute quantitation may be important in some situations; for example, in diagnosis of multivessel disease in myocardial perfusion SPECT studies. In PET, the currently used quantitation method, which estimate standardized uptake ratio, certainly requires further work and refinement before it reaches absolute quantitation level.

Currently, most hospitals perform dynamic studies using planar techniques (renal glomerular filtration rate, lung function), which unfortunately lack both 3-D resolution and proper attenuation correction. Ideally, dynamic functional studies should be quantitative and 4-D, which means that they should include, in addition to fully quantitative 3-D information, the time component. Such imaging capabilities are currently available for ring PET systems but are not widely used in standard clinical studies. Dynamic information is usually extracted from a series of tomographic images, each acquired quickly enough that the activity distribution may be assumed to remain constant (static) during the time of acquisition. Recently, fast-rotating triple head SPECT systems have been tested in this type of dynamic studies. Another dynamic SPECT method (dSPECT) allows for the reconstruction of 4-D dynamic series of images from a single slow camera rotation using modern iterative optimization techniques.

Dynamic functional quantitative studies may certainly be considered an advanced stage of nuclear imaging. Dynamic sequences, however, usually require large computer memory for data storage and fast processing capabilities. Kinetic parameters, which may be obtained from these dynamic data using compartmental modelling, certainly require more sophistication in both the understanding of the physiological processes and their mathematical description.

7. AVAILABILITY

All manufacturers of nuclear imaging equipment provide data acquisition and processing software. Clinical availability of more sophisticated techniques is for the moment quite limited, although the situation is constantly changing and improving, a trend that needs to be encouraged. Both the supplier and the user should be extremely cautious, however, when new products are being brought onto the market, as well as in the clinical use of new methodology. This is because techniques that are insufficiently tested may later create customer distrust or, in an extreme situation, result in serious health-related problems due to patient misdiagnosis.

8. BREADTH OF APPLICATION

Physiological processes are dynamic, with the distributions of the biological molecules changing over time. The rate of these changes is often important for the assessment of the organ function or the disease. Functional nuclear imaging allows for visualization of organ anatomy (normal or diseased) and measurements of metabolic rates of various biological processes, or to follow the movement of biological molecules during biodistribution and metabolism. Thus, applications of the technology range from imaging of anatomy, through studies of physiology and organ function, to the ultimate goal of molecular imaging.

9. COLLABORATORS

Potential sources of new ideas, techniques and methods are academic and hospital-based research groups supported mainly by research grants (federal, provincial and other). Close collaboration with industrial partners may allow for faster clinical implementation of new methods and more focus in research.

Hardware

1. GOALS

The scintillation camera is reaching the limit of cost-effective performance improvement. The scintillation crystal and photomultiplier tubes (PMTs) are the components that influence the performance of the cameras to the greatest degree. The light output of the crystal and the conversion into electrical signal (quantum efficiency) of the PMTs may yet improve (though only marginally), which would enhance the intrinsic resolution of the cameras. However, this would only make the diagnostic image better close to the collimator, as the limitation of the camera is the collimator. However, improvements in the crystal and PMTs would enhance energy resolution, which would increase image contrast and enable scatter estimation and correction methods to function more accurately. Commercial scintillation cameras are now reaching an energy resolution of 8.5 percent at 140 KeV (kiloelectron volts), which has implications for semiconductor cameras.

2. DESCRIPTION

Signal processing techniques in scintillation cameras are broadly similar, although the implementation affects the performance figures and differentiates the cameras. Spatial linearity and energy field corrections are now universal, and most scintillation cameras utilize one analogue to digital (A/D) per PMT. The centroid algorithm is the most widely used method to calculate the position of the event. Many scintillation cameras use regional A/D control to allow several groups of PMTs to function independently for higher count rate capability, especially during co-incidence studies.

Gantry design influences image quality through precision and reproducibility. Current gantry designs are quite varied, and the hardware assessment is difficult to quantify.

3. IMPORTANCE

The current market for nuclear imaging equipment is mainly composed of variable geometry dual-head scintillation cameras. A significant number are equipped with co-incidence capability for positron studies, particularly in the U.S. There is about one third the number of single-head compared to dual-head cameras, and three-head cameras comprise a small share of the market. The geographical distribution of the scintillation cameras varies worldwide and is significantly affected by procedure reimbursement. Dedicated positron emission tomography (PET) systems are increasing in number, and debate continues about the cost versus diagnostic accuracy of dedicated PET systems and co-incidence-equipped camera systems.

Semiconductor cameras have yet to come into clinical usage.

The use of electronic dispersion and storage of images and data is growing, but is still not universal.

Image fusion with other imaging modalities is also growing. Remote service of equipment is being introduced to varying degrees, depending on when the equipment was designed and whether all the components were designed at the same time.

4. CLINICAL REQUIREMENTS

Scatter estimation and correction enables more accurate measurement of quantitative data in clinical studies. Such methods have been proposed for quite some time, but few have been brought into routine clinical practice. These techniques tend to push the limits of scintillation camera technology requiring very good energy resolution, and the response of the camera has been energy independent. Meeting clinicians' needs will require improvements in scintillation cameras and may hasten the clinical introduction of semiconductor cameras.

5. MATURITY AND RISK

New scintillators are found everyday, and it is difficult to project the effect of such findings, but new scintillators could profoundly affect the course of nuclear imaging. Continued research in this field should be encouraged. The PMT and the photodiode score well in predictability when measured against the alternatives. The limitation of photodiodes is that as the area of photodiodes increases so does the noise, and this noise is caused by defects in the semiconductor material at the atomic level. This results in noise increasing as the square of the radius of the diode.

Single-photon imaging in nuclear medicine, being relatively mature, will see only gradual improvement unless a breakthrough to eliminate the collimator is made.

Imaging in positron imaging can expect, or at least push for, improvements, particularly in large area imaging and cost reduction.

6. BREADTH OF APPLICATION

There is a continuing need for both imaging and non-imaging probes for surgery and other applications, and it may be there that the future for semiconductor cameras lies.

7. COST-BENEFIT ANALYSIS

PET imaging, attenuation correction, scatter correction, image fusion and semiconductor cameras are likely areas of hardware improvements.

It is likely that the relative merits of co-incidence cameras and dedicated PET systems will drive improvements in both technologies, as both move towards a low-cost, high-resolution system for PET. With lower costs and higher performance, PET would become more widespread with FDG (fluorodeoxyglucose) and other positron pharmaceuticals becoming more readily available. The scintillation cameras can benefit from partially pixelated thick crystals available from the leading camera crystal manufacturer. These crystals improve detection efficiency at higher energies and reduce the loss of spatial resolution at lower energies. Scintillation cameras, particularly large-area dual-head systems, have a poor true-to-random-count ratio, limiting the clinical performance of these systems.

Pursuing the goal of lower cost/higher performance PET systems also presents challenges in terms of cost and efficiently imaging larger areas in the axial direction of the patient. Possible candidates for area imaging are TMAE (tetrakis-dimethylamino-ethylene) gas multiwire proportional systems with timing resolutions of three to four nanoseconds FWHM (full width at half measure).

Attenuation estimation systems continue to evolve, and the relative qualities of the various systems in use and under development continue to be debated. Recent developments have added dedicated X-ray CT units to scintillation cameras for both attenuation and image fusion applications. Further developments are anticipated in this direction to produce more accurate attenuation maps and reduce running costs.

The most promising semiconductor cameras at present are based on cadmium-zinc-telluride crystals. This is truly a semiconductor camera, converting the gamma photon into electricity directly proportional to the energy deposited in the crystal, and this without the intermediary light scintillation and subsequent light conversion into electricity by either a PMT or photodiode. This gives better energy resolution and the spatial resolution is defined by the size of the crystals arranged in an array. However, cost is also proportional to the size of the crystals and increases rapidly as the area to be viewed increases. A small area commercial unit was demonstrated but was withdrawn and replaced with a pixelated scintillator system with photodiodes. The future of the semiconductor camera remains to be seen.

Clinical Radiopharmaceutical Agents

1. DESCRIPTION

Nuclear medicine imaging is the clinical standard for examination of physiological function in patients with heart disease, cancer and neurological disorders. These measurements include such things as brain and heart perfusion (blood flow) and function, kidney function, bone density, cancer detection and staging. Imaging is performed by "labeling" the molecule of interest with a radioactive isotope. The PET isotopes 11C, 13N and 15O can be used to label virtually any molecule (or drug) used in the living body. Other PET isotopes, such as 18F, 64Cu and 82Rb, or SPECT isotopes, such as 99mTc, 201Tl and 123I, are used to label molecular "analogues," as these elements are not found naturally in biological compounds. A labelled molecule is called a radiopharmaceutical "tracer," and it is administered to a patient and imaged with SPECT or PET to measure its uptake and metabolism.

2. IMPORTANCE

Specific patterns of tracer uptake and metabolism are associated with disease in certain organs, such as the brain, heart, kidneys and bones. The growing availability of disease- and organ-specific imaging tracers will enhance the ability of physicians to diagnose disease early, then prescribe and evaluate the best therapy for individual patients.

3. MATURITY AND RISK

The clinical use of positron emission tomography (PET) for cancer and heart disease imaging has undergone tremendous growth over the past few years.

82Rb has been used for myocardial perfusion imaging to diagnose CAD (coronary artery disease) in the United States for more than 10 years. 82Rb is manufactured at one academic medical centre in Canada but is not yet distributed for clinical use. New tracers developed in the future could be distributed if they are labelled with 18F, which has a sufficiently long half-life (110 minutes) for transportation to imaging centres within five to six hours.

4. AVAILABILITY

Development and distribution of new tracers is dominated by multinational pharmaceutical companies, including Dupont Pharma and Nycomed-Amersham. However, there are small radiopharmaceutical development companies based in Canada as well. SPECT agents are commonly labelled with 99mTc, because it is well suited to imaging with NaI detector systems used in every nuclear medicine department. For example, the tracers Sestamibi1 and Myoview2 have become the standard for myocardial perfusion imaging to diagnose coronary artery disease. Pertechnetate2 is used for radionuclide angiography to measure myocardial function. Miraluma2 has been introduced for breast cancer imaging. Brain perfusion is measured with HMPAO, and kidney function is measured with DTPA. There are many other SPECT tracers distributed commercially, and several are manufactured in academic medical centres and distributed by the pharmaceutical companies.

In the U.S., several PET tracers such as 18F-fluorodeoxyglucose (18FDG) are now available for sale by commercial companies such as P.E.T.Net 3. In Canada, there is only limited supply of 18FDG from the academic medical centres that have the cyclotron facilities required to manufacture PET tracers.

5. BREADTH OF APPLICATION

Many tracers have been developed to examine various metabolic processes in health and disease. For example, 18FDG was originally developed for research studies of glucose metabolism in the brain and heart muscle, and is now available in the U.S. and Europe for cancer imaging. SPECT and PET tracers have been developed to measure oxidative metabolism, fatty acid and amino acid metabolism, and pre- and post-synaptic receptor densities. However, PET is unique in its ability to quantify these measurements in absolute physiological terms (e.g. substrate metabolism in mol/min/g). PET tracers have recently been adapted to image gene expression, which will become increasingly important in the assessment of new genetic therapies for cardiovascular disease and cancer. Investigation of these agents in the molecular biology laboratory includes imaging in animal studies. This has led to the development and use of small-animal PET and SPECT systems as an alternative to traditional autoradiography.

PET and SPECT imaging are widely used to evaluate the physiological effects of new pharmaceutical therapies in humans, including measurement of perfusion, substrate metabolism and receptor densities. PET is also playing an increasing role in the development stages of new drugs, when it used to perform biodistribution studies for the initial animal and human studies. New Tc-labelled SPECT radiopharmaceuticals can also be evaluated quantitatively with PET by labelling with 94mTc.

6. COST-BENEFIT ANALYSIS

As stated in the Working Group 1 report *Future Needs for Medical Imaging in Health Care*, 18FDG PET cost-effectively outperforms other imaging methods in staging many cancers. 18FDG is also recognized as the best tracer to assess ischemic viable myocardium that will benefit from revascularization with bypass surgery or angioplasty.

7. REFERENCES

1. Dupont Pharmaceuticals: http://www.dupontpharma.com
2. Nycomed-Amersham: http://www.nycomed-amersham.com
3. P.E.T.Net: http://www.petnetpharmaceuticals.com
4. University of Ottawa Heart Institute: http://www.ottawaheart.ca
5. Institute for Clinical PET: http://www.icppet.org

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Medical Imaging Technology

WG 2 - Final Working Group Report

ELECTROENCEPHALOGRAPHY AND MAGNETOENCEPHALOGRAPHY

1. TECHNOLOGY BACKGROUND AND DESCRIPTION

Electroencephalography

Electroencephalography (EEG) is a technique for measuring the electrical activity of the brain that is caused by the current generated within neurons. It was originally developed in 1924 by Hans Berger of Germany. To perform the measurement, a number of electrodes are placed singly or in pairs on the scalp. When the electrodes are placed singly, then one common "reference electrode" is used. Each electrode measures a voltage on the scalp, then transmits this signal, which is amplified and subsequently recorded. Originally, such recordings were made by a pen plotting the output on paper. Increasingly, the output is now being recorded by a digitizer and saved on a computer (digital EEG). For some applications, electrodes are placed under the scalp or in direct contact with the brain.

EEG can record the rhythmic fluctuation of the brain's electric potentials (for example, alpha waves in a relaxed person or slower waves during sleep), responses evoked from a particular stimulus (for example, a tone or flash of light), which is known as evoked response potentials (ERP), or pathological signals, such as sharp spikes from epileptic activity. The main functions for an EEG in a hospital are diagnosis, communication of information to clinicians and wards, education and research.

Magnetoencephalography

Magnetoencephalography (MEG) systems measure signals that arise from the same source as the electroencephalogram, namely the current generated within neurons, but whereas EEG measures the electric fields, MEG measures the magnetic fields that accompany the flowing current. One of the first MEG systems was operated at MIT for many years under the direction of David Cohen, a pioneer in the field of magnetoencephalography. Dr. Cohen, who is considered the inventor of the MEG system, first measured the magnetoencephalogram in 1968.

Unlike EEG, MEG requires no direct skin contact with electrodes. MEG uses a number of sensors that are brought in close proximity to the head. These sensors are immersed in liquid helium, contained within a cryogenic vessel called a Dewar. The very cold temperature of the helium (-273° C) allows the sensors to become superconducting and hence sensitive enough to detect the extremely tiny signals of the brain.

Originally, MEG systems consisted of only a few sensors that had to be arduously moved over the surface of the head to generate a "map" of brain activity. Prior to the 1990s, all systems available had less than about 30 channels and could cover only a portion of the subject's head. These systems had to be moved to a variety of positions, and co-registered in a very cumbersome manner, in order to create a montage of positions that spanned the entire cortex. Although MEG was embraced as a powerful modality for the study of the human brain by researchers, it was not considered practical for routine clinical work.

However, the technology has advanced rapidly in the last decade. In 1992, two MEG manufacturers introduced "whole-cortex" systems, followed by another in 1995. Such systems allow for the simultaneous recording of signals from the entire brain — an advance that cut recording times from several hours to several minutes and also increased accuracy. The first such system featured 64 sensing channels, but vendors now offer systems with more than 250 channels.

The other major advance was the development of dewars that operated effectively at a variety of angles, allowing the subject to either sit or lie down, whichever is more natural for the patient. This is particularly significant for clinical studies in which the patient may be immobilized. Other advances include such things as increased sample rates, the introduction of simultaneous EEG detection, and faster electronics for processing.

With the advances listed above, MEG has reached the point at which it is now a practical instrument for clinical work.

Differences and Commonalties

As stated, both MEG and EEG measure signals that arise from the currents within the brain — the electric field and the magnetic field. Both have excellent temporal resolution; that is, they can measure changes over a millisecond duration. Other functional brain imaging techniques such as fMRI and PET have much poorer temporal resolution because they essentially measure blood flow or oxygenation, which are much slower processes than neuronal activity.

In current clinical practice, EEG constitutes almost all data activity in a hospital, in contrast to MEG, which is still mainly limited to research activities; however MEG's clinical use is increasing. MEG technology is not viewed as a replacement for EEG, due to its much higher cost and the need for the head to be motionless during recording, but rather as a complementary measure in complex cases, or those for which EEG is otherwise not sufficient.

EEG's effectiveness as a research tool is limited because it records only a small sample of electrical activity from the surface of the brain and the signals are distorted by the conductivity of the scalp. Electroencephalography has proved itself useful as a diagnostic aid in cases of serious head injuries, brain tumors, cerebral infections epilepsy, and various degenerative diseases of the nervous system. MEG, while a much more expensive technology, can be used for such diagnoses and also complex cognitive measurements.

Despite the differences, there are many issues for which technology concerns are common to both MEG and EEG.

2. AVAILABILITY AND MATURITY

EEG is currently available in all major hospitals worldwide, numbering in thousands of installations. There are currently also a large number of EEG equipment manufacturers throughout the world, including a Canadian company, XLTEK, of Oakville, Ontario. The cost of a unit ranges from tens of thousands to one hundred thousand dollars.

The basic technology of EEG has been mature for decades. Recent incremental advances have included digital operation, new and better electrodes, high-density electrode arrays (which allow for brain signal mapping and limited localization ability) and electronics/amplifier improvements — including faster sampling with better signal resolution.

MEG is currently available in approximately 80 hospitals or research centres worldwide. This figure is increasing at a rate of about 15 installations per year. The sites are generally world-renowned, large facilities located in Japan, western Europe, the United States and Canada. There are currently only a handful of MEG manufacturing companies throughout the world, one of which is a Canadian company, CTF Systems Inc., of Port Coquitlam, British Columbia. Cost of a unit is in the range of $2–3 million.

MEG's maturity into an instrument capable of routine clinical examination has occurred within less than the last decade. As outlined in the previous section, the large number of simultaneous sensors and the supine measurement position option have been the significant developments to enable this transition. Developments in electronics, allowing faster sampling with better signal resolution, have taken place in MEG as well.

3. ALTERNATIVE AND COMPLEMENTARY TECHNOLOGY

MEG and EEG are both electrophysiological function brain imaging technologies. That is, they measure the electrical activity of the brain under certain conditions, after a stimulus or during a pathological event. Some other brain imaging techniques give structural or anatomical information only and are complementary to the functional information (MEG and EEG give no information about brain structure). Other techniques measure blood flow or oxygenation, which is also a measure of brain function, but at a much lower temporal resolution. MEG and EEG are the only functional imaging modalities that are a direct measure of neural activity. MEG signals, because they are not distorted by the conductivity of the scalp as EEG signals are, may also be used to make accurate spatial maps and localizations of brain activity.

MEG and EEG are also non-invasive (except when EEG electrodes are placed subdurally or deep within the brain — a highly invasive technique suitable for clinical cases only), non-hazardous technologies with no radioactivity, injections or applied magnetic fields.

The cost of an EEG procedure is rather low because it uses no expensive consumables, such as radioisotopes. The cost of an MEG examination is similar, excluding equipment cost. The time-consuming step of placing and localizing a large numbers of electrodes is unnecessary with MEG.

The following is a list of some common brain imaging technologies currently available contrasted with MEG and EEG.

Magnetic Resonance Imaging

- Gives anatomical information and, as such, is complementary to MEG and EEG.
- No information about function.
- Possible hazard, especially to children or pregnant women, due to high RF (radiofrequency) and magnetic fields.
- Cost of equipment is comparable to that for MEG but much higher than that for EEG.
- Cost of procedure is comparable to that for MEG and EEG.

Computed Tomography

- Gives anatomical information and, as such, is complementary to MEG and EEG.
- No information about function.
- Possible hazard, especially to children or pregnant women, due to X rays.
- Cost of equipment is comparable to that for MEG but much higher than that for EEG.
- Cost of procedure is comparable to that for MEG and EEG.

Functional Magnetic Resonance Imaging

- Measures blood flow or blood volume, rather than electrophysiology.
- Has a temporal resolution on the order of one second, which is much worse than MEG or EEG.

Therefore, it cannot easily measure fast phenomena such as alpha rhythms or epileptic spikes.
- Possible hazard, especially to children or pregnant women, due to very high RF and high magnetic fields.
- Cost of equipment is comparable to that for MEG but much higher than that for EEG.
- Cost of procedure is comparable to that for MEG and EEG.

Note: some centres are currently beginning to successfully combine MEG/EEG information with that from functional MRI.

Positron Emission Tomography

- Measures metabolism of oxygen or sugar, rather than electrophysiology.
- Has a temporal resolution on the order of one second, which is much worse than MEG or EEG. Therefore, it cannot easily measure fast phenomena such as alpha rhythms or epileptic spikes.
- Possible hazard, especially to children or pregnant women, due to ionizing radiation from ingested radionuclides.
- Measurements cannot be repeated after annual maximum dose is reached (generally one examination).
- Cost of equipment is much greater than that for either MEG or EEG (to perform PET, a cyclotron or other accelerator is required).
- Cost of procedure is much greater than that for either MEG or EEG (significant numbers of staff are required to operate the cyclotron, make radiopharmaceuticals and measure patients).

Single Photon Emission Computed Tomography

- Measures blood flow, rather than electrophysiology.
- Has a temporal resolution on the order of one second, which is much worse than MEG or EEG. Therefore, it cannot easily measure fast phenomena such as alpha rhythms or epileptic spikes.
- Possible hazard, especially to children or pregnant women, due to ionizing radiation from ingested radionuclides.
- Cost of equipment is less than that for MEG, but greater than that for EEG.
- Cost of procedure is comparable to that for MEG and EEG.

4. CLINICAL APPLICATIONS

EEG and, to a lesser extent, MEG are currently used routinely in clinics throughout the world for the pre-surgical localization of critical brain regions, and for the non-invasive localization of epileptiform activity. For MEG, many clinical research teams are working to expand the number of functional brain regions that can be routinely localized, as well as to characterize magnetic abnormalities that accompany a wide variety of cerebral diseases. The non-invasiveness of MEG and EEG means that they can be used for screening and repetitive follow-up measurements without concern for adverse effects.

As procedures for activating various functional brain regions are standardized, and as the effects of specific cerebral diseases on the MEG are carefully documented in controlled studies, the number of routine medical applications for MEG will increase significantly. In the future, neuropsychological testing may be a key element of all medical applications of MEG. This will extend well beyond the sensory mapping of the primary sensory cortex as currently practised. It will include characterization and localization of higher sensory and motor areas, intermodal processing regions, and all aspects of attention, memory, affect and cognition. Specific clinical applications will include migraine and headache aphasias, agnosias, perceptual disorders, neglect syndromes, dementias (including organic brain syndrome) and developmental disorders. Future possibilities include the study of Alzheimer's, autism, multiple sclerosis, cerebral palsy, Parkinson's, chronic pain and stroke.

Beyond clinical work, there continues to be a large volume of work performed in basic brain research with these technologies. The ultimate goal is to generate a full understanding of how the brain functions under many varied situations and tasks.

A new application for MEG, which is not possible for EEG or any other known technology, is the detection of brain, heart and other signals from the fetus. This has applications for research as well as treatment decisions for high-risk pregnancies. Obstetrical applications could include: fetal MEG, fetal-evoked potentials, fetal breathing, fetal MCG (heart signals), fetal movement and uterine contractions (premature labour). Other reproductive health applications could include fallopian tube motility, reproductive cancer detection, bladder contractions and vaginal contractions.

5. GOALS AND ISSUES FOR FUTURE DEVELOPMENTS

Data Format/Network

In both MEG and EEG, a great deal of data can be generated in a relatively short period of time. As the number of patients examined grows, the need to establish data volumes and networks of sufficient capacity becomes important.

For example, a routine digital EEG of approximately 30 minutes with 21 scalp channels requires on average 15–20 MB of data per examination. Comparable or larger data sizes are generated by MEG. A hospital may have four to six EEG test rooms, with four records generated per day from each. This results in about 100 GB per year in routine EEG data alone. However, with the addition of digital video (at a data rate of 1 GB per hour), which will likely be adopted by hospitals within five years, the same hospital would generate 2600 GB per year. With operating room, sleep, and/or intensive monitoring, the data volume may double. In addition to this, patient information data (including history, clinical profiles and demographics) will need to be incorporated. Although the data volume is small, it is critical, and of interest to many people.

All this data should be accessible within the hospital (through a hospital-wide LAN), city (from physicians' homes and outside the hospital) or country (by outside experts) by a fast, secure transfer. The method should be cost-effective and allow for convenient archive and back-up. For it to be effective, there must be a set of archival standards is media- (currently including CD-ROM, DVD and digital tape), platform-, hospital- and system vendor-independent. The selection of such standards should not ignore market-driven forces.

For EEG and MEG, post-processing needs for the data include simple visual interpretation, but also sophisticated computer head models, complex mathematical manipulation, and co-registration with anatomical MRI data. Easy access, transfer and communication between different groups become essential. Distributed data allows easier integration with other functional imaging technologies, such as fMRI and PET, to take advantage of MEG and EEG's superior temporal resolution, while retaining the more direct measurement of location available from other technologies.

In the future, there will be increased use of real-time, multimodality technology for the measurement of brain function in awake individuals. The real-time requirement will mandate high-speed data movement. Also, in-home monitoring with an Internet feed to hospital departments will increase, reducing the need for hospitalization.

Data Exchange

A good deal of the processing of MEG data is proprietary and specific to particular systems. The consequence of this is a reduced capability of universal analysis of the same data. If all MEG data were in a standard format, anyone could extend utilization of the data to investigate questions that were not part of the experiments that originally produced the data.

As an example, one laboratory may have collected data and come to conclusions with respect to a configuration of sensors. Another laboratory, not having collected the data, could nonetheless analyze the data with respect to another configuration of sensors.

A difficulty of this approach is not necessarily specific to MEG — that is, that researchers frequently think of their data as proprietary and not subject to analysis by others. However, the transfer of data between laboratories, even if it is agreed to by different laboratories, is made difficult by the current requirement to transfer data in formats that do not require system-specific analysis tools.

Standards of data exchange must be established for the growth of MEG technology and the corresponding clinical and scientific techniques.

Hardware

Although EEG technology is relatively mature, additional research must be applied to study new and better techniques in several areas: The field would benefit from an improved analogue front end and new electrode technology. Amplifier technology also requires continual improvements.

Connectivity, for the reasons described above, including local and wide area networks, must be augmented. Data compression, encryption and translation solutions, together with archival technology to replace CD, DVD and DAT should be investigated to prepare for the coming massive increase in data volumes. These developments would benefit MEG, EEG and other medical imaging modalities. If wireless transmissions begin to proliferate within the hospital environment, radio waves would require regulation.

Multiprocessor computer functionality for solving more difficult clinical demands and problems is required. Many complex data processing techniques in MEG and EEG are hampered by insufficient computing speed. Increased speed in dedicated electronics architecture to assist in these computationally expensive algorithms would also be of use.

Currently most MEG installations use costly, very massive "magnetically shielded rooms" to shield the systems from environmental signals, which are many orders of magnitude larger than the signals from the brain. Research time and money needs to be invested into finding improved methods of noise cancellation to eliminate the need for this expensive room. Hospital siting issues would also be eased with the elimination of the shielding.

MEG systems are substantially "handmade" in relatively low quantities, at rather high cost. As sales volumes grow, greater levels of automation in production should be implemented to reduce overall system cost. A decrease in costs will further enhance the growth of MEG technology.

In both EEG and MEG, developments to increase the number of detectors in the top-end systems will likely be ongoing. This requirement is largely market-driven by the high-end research user. Systems built for routine clinical use will likely be satisfactory with the number of sensors and channels currently offered.

Localized Versus Distributed Systems

A primary emphasis in MEG research has been the estimate of equivalent dipole sources (ECD). A dipole source is said to be the "centre of gravity" of more distributed or more localized systems. This assumption came from EEG, although EEG methodologies do not depend on this assumption as universally as do MEG methodologies. The emphasis of this assumption was originally driven by the use of MEG for the study of epilepsy, in which it was assumed that the activity was frequently focal in the sense that a localized pathological source was to be found. This assumption may be true for some forms of epilepsy, and other brain pathology, but it is almost always not true in normal brains engaged in complex information processing, where widely distributed systems are involved.

Even in when sensory function or motor systems are studied, it is clear that the nature of the processing in a sensory system (e.g. a visual system), or in an output system (e.g. supplementary motor systems), must involve distributed systems. The simple fact that the analysis of the signals from these systems looks at components of signals in the range of 100 to 500 msec after sensory input, or preceding motor output, must lead to the conclusion that the systems are distributed. Sensory input reaches the cortex in less than 60 msec and there is widely distributed activity by 100 msec and certainly spontaneously changing activity of many seconds preceding output — especially when the output is complex like that of language or non-preprogrammed motor output.

There are current methodologies intended to analyze distributed systems, some of which are purported to estimate 3-D attributes of those systems. However, these analysis systems are not yet as widely accepted as is dipole analysis, primarily because the mathematics of dipole analysis has fewer non-physiological assumptions.

New Analysis Techniques

With MEG technology, the hardware available has advanced more quickly than the analysis techniques to process the data. As stated above, MEG has traditionally been analyzed using the ECD approximation. This method presupposes the activity in the brain comes from a small number of sources and is well localized. While this may be a good approximation for sensory-evoked and motor activity, it is not satisfactory for studying more complex cognitive or associative phenomena. It is also not suitable for studying spontaneous activity within the brain (i.e. without averaging around an externally measurable event).

Given the state of the MEG hardware available today, a great deal of effort is being expended by researchers (and the equipment manufacturers themselves) to develop new and more powerful techniques that take advantage of the large number of low-noise MEG sensors at hand in modern systems. This includes development of techniques that take into account the special array properties of the current high-density systems available. Algorithms from radio astronomy, for example, have been implemented with promising results. Also, certain automated techniques have been developed for which very little prior knowledge of the source must be assumed, thus allowing relatively modest amounts of intervention between data acquisition and image generation. Also, development of automated techniques for which very little prior knowledge of the source must be assumed, and therefore allow relatively modest amounts of intervention between data acquisition and image generation.

Many of the most critical advances that are required to bring MEG to the next level of clinical acceptance and marketability will be within the data interpretation or software, rather than the equipment. EEG also has new and powerful analysis techniques under development.

Spontaneous vs Event-related Activity

To date, the primary focus of MEG has been event-related activity. However, there are good theoretical reasons for the assertion that this methodology is limited and may indeed result in erroneous conclusions about brain function.

The original emphasis on event-related activity was driven to some extent by the use of averaging methodologies to enhance noise reduction. The technique of using averaged event-related activity with respect to sensory input, or response output, is still a primary approach in most laboratories. The assumption of signal averaging is that the signal of interest is the same at each occurrence of its observation — that is, that the brain responds the same way each time the same stimulus is presented or that brain processing is the same preceding output.

The question has arisen as to whether averaging defines the signal rather than represents the signal — that the true signal is one that is in a constant process of modification, based not only on the influence of the repetition of the input (or output), such as the influence of memory systems, inhibitory processes and others, but also because the basic characteristic of neurophysiology is variability of response. The concept is that variability is not a form of random noise but an important attribute of the way in which processing occurs.

To date, MEG has had limitations with respect to its capability for resolving spontaneous activity because it depends to a greater extent than do other technologies on averaging to facilitate "noise" reduction. Some of the techniques described in the previous section must be further investigated, implemented and clinically accepted to overcome these limitations.

Training

With the rather recent changeover to digital EEG, the need for additional staff training has become evident. Technicians need to be trained in computer and digital EEG methodology. MEG is a relatively new technology, so the need for education is particularly acute; very few centres worldwide offer dedicated MEG training. Both modalities require constant delivery of education modules and maintenance.

At some new MEG centres, it has been difficult to find sufficiently trained staff to run equipment and produce meaningful results. Universities and other educational bodies must be encouraged to offer courses to mitigate these difficulties.

6. GOVERNMENT ASSISTANCE

In the past, the Canadian government actively assisted companies with the development and implementation of new medical technology. This funding and assistance has largely disappeared in the recent years, although a tax credit, in the form of the Scientific Research and Experimental Development Program (SR&ED), has endured.

The recent Canadian Foundation for Innovation (CFI) grants have allowed domestic hospitals and universities to acquire MEG and EEG technology from Canadian companies, which they otherwise would not have been able to purchase. This has resulted in several million dollars of MEG and EEG system sales (however, with "in-kind" contributions from the manufacturers).

Because most MEG and EEG systems manufactured in Canada are destined for export, strong support from the government has been required. The Canadian Company Capabilities (CCC) database, the Export Development Corporation (EDC), and various Canadian embassies have been invaluable in generating sales to foreign markets.

7. IMPACT OF STANDARDS AND REGULATIONS

Because MEG and scalp EEG are non-invasive technologies, standards and regulations are less onerous than techniques that, for example, expose a patient to radioactive isotopes or strong fields. They are passive detectors that measure brain activity, but do not expose the patient to any potentially harmful influences.

In Canada, both MEG and EEG systems must pass CSA International (formerly the Canadian Standards Association) tests to ensure that sufficient safeguards against electrical shock to the patient and operator exist. A medical device registry also exists. In the U.S., all devices marketed as medical equipment must pass Food and Drug Administration approval. Similar regulations exist in other countries. However, MEG and EEG systems, from a variety of vendors, have such approvals and these have not proven to be a significant barrier to marketing.

With the increasing adoption of the ISO standard, all companies manufacturing medical systems will eventually have to adopt manufacturing standards if they hope to be competitive in the global marketplace.

8. THE FUTURE

EEG technology will certainly remain one of the mainstays of hospital diagnostic procedure and pre-surgical planning. With the recommended improvements to hardware, and especially data volumes, the technique will continue to increase its value as a tool to assist doctors in improving the quality of life for a wide variety of patients into the foreseeable future. Its relatively low cost, high temporal resolution and non-invasiveness make it especially attractive.

MEG technology is emerging from the research-only regime as a powerful new tool that can augment the information from EEG with the ability to precisely localize sources of brain signals. It also features the non-invasiveness and high temporal resolution of EEG but without the signal distortions from the scalp. Its usefulness as a research tool will continue, shedding light on the mysteries of the brain's workings, while allowing the clinician to treat complex cases and an ever-expanding number of conditions.

9. CONTACTS (see Appendix B for further information)

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Medical Imaging Technology

WG 2 - Final Working Group Report

ULTRASOUND

- Contrast Agents
- Scanners
- Scanner/Sonographer Interface

Contrast Agents

1. GOALS

This section outlines the composition, role and availability of microbubble contrast agents for ultrasound, summarizes the current indications for their use, describes the impact of these agents on ultrasound scanner technology, and assesses some current areas of active development.

2. DESCRIPTION

Contrast agents for ultrasound comprise microbubbles of gas stabilized by a shell of biocompatible material such as a protein, lipid or polymer. The bubbles are smaller than red blood cells and are therefore suitable for intravenous injection. Their function is to alter the character of the scattering of blood by ultrasound, by increasing the backscatter cross-section and adding a nonlinear component. These means allow specialized imaging methods to preferentially detect the echo from the agent while suppressing that from other structures, such as solid tissue. The result is that the combination of contrast agents and new nonlinear imaging methods is capable of detecting and displaying echos from the microcirculation of, for example, the myocardium, in real time.[1]

2.1 Contrast Agents

Types of Contrast Agents
Contrast agents might act by their presence in the vascular system, from which they are ultimately metabolized ("blood pool" agents), or by their selective uptake in tissue after a vascular phase. Of the properties of tissue that influence the ultrasound image, the most important are backscatter coefficient, attenuation and acoustic propagation velocity.[2] Most agents seek to enhance the echo by increasing the

backscatter of the tissue that bears them as much as possible, while increasing the attenuation in the tissue as little as possible, thus enhancing the echo from blood. A perfect blood pool agent displays the same flow dynamics as blood itself, and is ultimately metabolized from the blood pool. Agents can be made, however, that are capable of providing ultrasound contrast during their metabolism, as well as while in the blood pool ("selective uptake" agents). Colloidal suspensions of liquids such as perfluorocarbons and certain agents with durable shells[3] are taken up by the reticuloendothelial system from which they are ultimately excreted. There, they may provide contrast from within the liver parenchyma, demarking the distribution of the Kuppfer cell. Such agents with a cell-specific pathway have the potential to be used as a means to both detect and deliver therapeutic agents to a specific site in the cardiovascular system.

Properties of an Ideal Blood Pool Contrast Agent

- Nontoxic
- Intravenously injectable, by bolus or infusion
- Stable during cardiac and pulmonary passage
- Remain within the blood pool or have a well-specified tissue distribution
- Provide a duration of effect comparable to that of the imaging examination
- Have a narrow distribution of bubble diameters
- Respond in a well-defined way to the peak pressure of the incident ultrasound

Current Formulations of Blood Pool Agents

The four methods by which contrast microbubbles are made are shown below in rough chronological order, together with their current status.

Formulation	Characteristics	Status
Free gas bubbles	Could not traverse cardiopulmonary beds	Early agents no longer used
Encapsulated air bubbles	Successful transpulmonary passage	Includes currently approved agents (e.g. Levovist™)
Encapsulated low-solubility gas bubbles	Improved stability	Includes currently approved agents (e.g. Optison™)
Particulate (e.g. polymershell) gas bubbles	Controlled acoustic properties	Under development

Summary of Principal Manufactured Contrast Agents as of October 2000

This list is not complete, but gives an indication of the widespread commitment of the pharmaceutical industry to ultrasound contrast.

Manufacturer	Name	Formulation (Shell/gas)	Development Stage
Acusphere	AI-700	Polymer/perfluorocarbon	Preclinical development
Alliance/Schering	Imavist®	Surafctant/perfluorohexane/air	Late clinical development
Bracco	SonoVue™	Phospholipid/sulphur hexafluoride	Late clinical development
Byk-Gulden	BY963	Lipid/air	Not commercially developed
Cavcon	Filmix™	Lipid/air	Preclinical development
DuPont Pharmaceutical	Definity™	Liposome/perflouoropropane	Late clinical development
Mallinckrodt Medical	Optison®	Sonicated albumin/perflouoropropane	Approved in the E.U. and U.S. for cardiology indications
Mallinckrodt Medical	Albunex®	Sonicated albumin/air	Approved in the E.U., U.S. and Canada
Nycomed	Sonazoid™	Lipid/perfluorocarbon	Late clinical development
Point Biomedical	Bisphere®	Polymer bilayer/air	Clinical development
Porter	PESDA	Sonicated albumin/perfluorocarbon	Not commercially developed
Quadrant	Quantison™	Spray-dried albumin/air	Pre-clinical development
Schering	Echovist®	Galactose matrix/air	Approved in the E.U. and Canada
Schering	Levovist®	Lipid/air	Approved in 65 countries (not the U.S.) for cardiology and radiology indications
Schering	Sonavist®	Polymer/air	Clinical development
Sonus Pharmaceutical	Echogen™	Surfactant/dodecafluoropentane	Withdrawn in October 2000

Preparation and Administration

Contrast agents may be provided ready for reconstitution by simple addition of water or saline, or they may require more elaborate preparation, such as mixing in a mechanical shaker. In all cases, the injectate must be prepared immediately before use, as the bubbles are stable for a limited time. Injection may be as an intravenous bolus in a peripheral vein, usually in the forearm. A typical injection volume varies between about 0.5 ml for Definity to about 10 ml for Levovist. In all cases, tolerance is extremely good, with more than 100 000 injections having been performed without serious adverse events. Because of the low volume of injectate, a saline flush is generally used. The effect of the bubbles is relatively brief, lasting for about three minutes for an air-based agent such as Levovist, and for about five minutes for a perfluorocarbon agent such as Optison. The duration of effect can be increased by slow injection or infusion of the agent (e.g. by a drip). Infusions can be difficult to achieve with some agents because of the tendency of the bubbles to float or dissolve upon dilution. At present, administration by infusion remains an area of research.

2.2 Indications for Ultrasound Contrast Agents

The formal indications for use of contrast agents, as new drugs, are determined by government regulation. At present, there are only a limited number of approved indications, including the following:

- enhancement of echos from nonvascular structures such as fallopian tubes;
- enhancement of Doppler signals in examinations with a poor signal-to-noise ratio (e.g. renal arteries, cardiac valves and pulmonary veins); and
- an aid to B-mode delineation of the endocardial border in echocardiographic studies of left ventricular function.

However, there is strong evidence in the literature that contrast agents can provide information about microvascular flow and perfusion not currently obtainable using conventional ultrasound techniques. Such indications include, but are not limited to the following:

- myocardial perfusion
- tumourblood supply in organs such as the breast and prostrate; and
- liver lesion detection and characterization.

2.3 Mode of Action of Microbubbles in an Acoustic Field

Microbubble contrast agents are unique in medical imaging in that they interact with the scanning process. The nature of this interaction depends on the scanning parameters, principally the peak rarefactional pressure and the ultrasound frequency. A combination of these parameters is reported by the Mechanical Index (MI), estimated and displayed on all approved scanners. At low MI, bubbles undergo resonant radial oscillation in the sound field, returning a strong echo to the transducer. At higher MI, this oscillation becomes nonlinear, so that the bubble echos contain harmonics. At the maximum MI in the diagnostic range, many bubbles are disrupted by the acoustic field, producing a strong nonlinear echo before they disappear. These three regimes of bubble behaviour are summarized in the following chart:

Peak negative pressure (approx.)	Mechanical Index (MI) @ 1 MHz	Bubble Behaviour	Acoustic Behaviour	Application
< 100 kPa	< 0.1	Linear oscillation	Backscatter enhancement	Doppler signal enhancement, cardiac cavity opacification
100 kPa to 1 MPa	0.1 to 1.0	Nonlinear oscillation	Harmonic backscatter	Coronary artery Doppler, real-time cardiac cavity opacification, real-time myocardial perfusion imaging
> 1 MPa	> 1.0	Bubble disruption	Transient harmonic echoes	Intermittent myocardial perfusion imaging, postvascular liver imaging

2.4 Impact of Contrast Agents on Scanner Design

Harmonic Imaging

The nonlinear echoes produced by ultrasound contrast agents present an opportunity to create a method that can distinguish the echoes due to contrast from those due to linear tissue. The simplest of these methods — harmonic imaging — is now widely available on ultrasound scanners. In harmonic mode, the system transmits normally at one frequency, but is tuned to receive echos preferentially at double that frequency, whereas the second harmonic echoes from where the bubbles lie. Typically, the transmit frequency lies between 1.5 and 3 MHz and the receive frequency is selected by means of a bandpass filter whose centre frequency lies between 3 and 6 MHz. Harmonic imaging uses the same array transducers as conventional imaging does, and in most of today's ultrasound systems involves only software changes. Echoes from solid tissue, as well as red blood cells themselves, are suppressed. Real-time harmonic spectral

Doppler and colour Doppler modes have also been implemented on a number of commercially available systems and show a level of tissue motion suppression not available in conventional modes. Using harmonic power, Doppler flow in 40 um vessels can be detected in the moving kidney.

Pulse Inversion Imaging

Harmonic imaging imposes some fundamental limitations on the imaging process that restrict its clinical performance. These are overcome in pulse inversion imaging, in which two pulses are sent in rapid succession into the tissue; the second pulse is a mirror image of (i.e. 180° out of phase with it) the first. Echoes from linear scatterers such as tissue cancel, whereas those from bubbles do not. The resulting images show high sensitivity to bubbles at the resolution of a conventional image. Many scanners now offer some form of pulse inversion imaging.

Pulse Inversion Doppler

By detecting overlong bursts of inverted pulses and using Doppler detection methods, very high sensitivity to bubbles can be achieved so that bubbles can be detected at sufficiently low incident power levels to avoid destroying them. This opens the way to real-time perfusion imaging. Pulse inversion Doppler has demonstrated the first real-time images of myocardial perfusion using perfluorocarbon gas agents.

2.5 Cost

Cost is a potential issue for ultrasound contrast. At an approximate cost of $100 per dose, ultrasound contrast agents currently cost about as much as the ultrasound imaging examination itself. This high cost will only be justified once studies have demonstrated that the use of contrast obviates the need for a more expensive examination such as CT, MR or nuclear medicine.

3. IMPORTANCE

The addition of contrast agents to ultrasound extends the information obtainable to flow at the perfusion (i.e. arteriolar and capillary) level of the circulation. This cannot be achieved with conventional ultrasound, nor in real time, by any other currently available medical imaging modality.

4. CLINICAL REQUIREMENTS

The use of contrast agents places additional demands on the clinical use of ultrasound. These demands include upgrades to conventional ultrasound scanners, additional personnel to establish and operate the IV insertion, additional training of sonographers, and additional cost.

5. AVAILABILITY

Only some approved contrast agents are widely available. For example, of the two currently approved for use by Health Canada's Health Protection Branch — Levovist and Optison — only Levovist is marketed.

6. BREADTH OF APPLICATION

Potential areas of application of ultrasound contrast agents, in approximate rank of importance, are echocardiography, hepatic sonography, renal sonography, transcranial Doppler, breast and prostate sonography, and sonohysterosalpingiography.

Future developments in the combination of microbubble agents with drug delivery systems may take applications into intravascular (e.g. thrombolytic) therapy, chemotherapy and gene therapy.

7. IMPACT OF STANDARDS AND REGULATIONS

Regulatory approval from the relevant government agencies (in Canada, the Health Protection Branch) is required for the commercial marketing of contrast agents. In the United States, the Food and Drug Administration (FDA) is currently causing a considerable delay in the approval of contrast agents. At the time of writing, at least four agents with an "approvable" status still await final approval from the FDA. Now specific concerns over safety or efficacy have been expressed publicly. Extended delays from the FDA could have a detrimental effect on the future of ultrasound contrast.

8. REFERENCES

General

Becher H, and Burns P. 2000. *Handbook of Contrast Echocardiography: LV Function and Myocardial Perfusion* (Berlin: Springer Verlag) (also available at http://www.sunnybrook.utoronto.ca/EchoHandbook).

Cited References

Tiermann K, Lohmeier S, Kuntz S. et al. 1999. "Real-time contrast echo assessment of myocardial perfusion at low emission power: first experimental and clinical results using power pulse inversion imaging," *Echocardiography*, 16:799–809.

Ophir J, Parker KJ. 1989. "Contrast agents in diagnostic ultrasound."*Ultrasound Medicine and Biology*, 15:319–33. (published erratum in 1990: *Ultrasound Med Biol*, 15:319–333)

Fritzsch T, Hauff P, Heldmann F, Lüders F, Uhlendorf V, Weitschies W. 1994. "Preliminary results with a new liver specific ultrasound contrast agent." *Ultrasound Medicine and Biology*, 20:137.

Kaul S. 1997. "Myocardial Contrast Echocardiography: 15 Years of Research and Development." *Circulation*, 96:3745–3760.

Burns PN, Powers JE, Hope Simpson D et al. 1994. "Harmonic power mode Doppler using microbubble contrast agents: an improved method for small vessel flow imaging." *Proceedings: IEEE UFFC*, 1547–1550.

Hope Simpson D, Chin CT, Burns PN. 1999. "Pulse Inversion Doppler: A new method for detecting nonlinear echoes from microbubble contrast agents." *IEEE Transactions UFFC*, 46:372–382.

Becher H, Burns PN. 2000. *Handbook of Contrast Echocardiography*,(Berlin: Springer), p. 198.

Wilson SR, Burns PN, Muradali D, Wilson J, Lai X. 1999. "Microbubble contrast agents and harmonic imaging of the liver: imaging features in 30 patients with known hemangioma, hepatocellular carcinoma and liver metastases." *Radiology*, in press.

Correas J, Lafortune M, Burns PN, Pourcelot L. 1996. "Detection of renal artery stenosis with B-mode enhancement after administration of a US contrast agent." *Radiology*, 201:218.

Bauer A, Becker G, Krone A, Frohlich T, Bogdahn U. 1996. "Transcranial duplex sonography using ultrasound contrast enhancers." *Clinical Radiology*, 51:19–23.

Cosgrove D. 1996. "Ultrasound Contrast Enhancement of Tumours." *Clinical Radiology*, 51:44–49.

Schlief R, Deichert U. 1991. "Hysterosalpingo-contrast sonography of the uterus and fallopian tubes: results of a clinical trial of a new contrast medium in 120 patients." *Radiology*, 178:213–215.

Unger EC, McCreery TP, Sweitzer RH. 1997. "Ultrasound Enhances Gene Expression of Liposomal Transfection." *Investigative Radiology*, 32:723–727.

Scanners

1. GOALS

Ultrasound exams are now routinely used as a diagnostic tool in almost every specialty in medicine. The popularity of ultrasound as a diagnostic modality can be attributed to its noninvasive nature coupled with the cost-effectiveness of the scanners. In the last 20 years, ultrasound scanners have made great strides in both accuracy and ease of use. Ultrasound, by definition, is a real-time imaging modality and the aim of any well-designed ultrasound scanner is to allow for rapid patient throughput without compromising diagnostic efficacy. The goal of this report is twofold:

- to understand what is currently available in ultrasound scanners; and
- to identify enabling technologies that need to be pursued to fulfil clinical and patient needs.

2. DESCRIPTION

A brief description of the technologies most useful to the generation of ultrasound images is presented in this section.

2.1 Resolution: Contrast and Spatial

Ultrasound companies are concentrating on the development of systems that provide superior contrast and detail resolution (hereinafter simply referred to as resolution). The resolution of an ultrasound system is determined by the transducer geometry, firmware and tissue characteristics of the insonated volume. In an effort to improve image quality, ultrasound companies have spent much effort on the design of better transducers and improved firmware. Today, most transducers are simple 1-D arrays that have the major drawback of being electronically steered and focussed in a single plane. Indeed, focussing in the elevation plane is normally achieved by using an acoustic lens with a fixed focus. To solve this problem, researchers have been investigating the utility of 2-D arrays that, in principle, can focus and steer in three dimensions. The development of 2-D arrays is hindered by the need to integrate a large number of small elements into an ergonomically shaped transducer. An intermediate step in the move to 2-D arrays is the development of 1.5-D arrays. These arrays have fewer elements in the elevation direction, which means that they only provide limited focussing, but no steering in this direction. The complexity and high cost of building 2-D arrays have resulted in research into the viability of using sparse 2-D arrays to achieve acceptable resolution. Another issue that must be considered with the introduction of 2-D arrays is their weight and shape. Care must be taken when designing these transducers to ensure that the likelihood of repetitive stress injury is minimized.

Already, companies such as Siemens have introduced multidimensional arrays (e.g. VFX13-5 and CX5-2). Companies such as ATL have taken a slightly different tact when it comes to improving the resolution of their systems. Using lessons learned from CT and MR, ATL's new SonoCT Real-time Compound Imaging system obtains coplanar, tomographic images from nine viewing angles, then combines them into a single image. The averaging of the nine views results in reduced speckle, clutter and noise, reinforcing real structures. The net result is images with improved resolution. Combining this technology with 2-D arrays could lead to further improvements in image quality.

2.2 Operating System and Hardware

Traditionally, ultrasound systems have been analog devices. Today, all new systems are digital, allowing for easy software upgrades. The use of custom operating systems is a thing of the past, with newer systems such as Hitachi's EUB 6000 utilizing off-the-shelf operating systems such as Microsoft's Windows NT. This enables quicker software development and allows ultrasound companies to more easily outsource development costs. Indeed, companies such as GE upgrade their systems annually. In the rapidly changing and cost-conscious health care market, there is always a need to look for ways to cut cost and speed up time to market. The move to a standard operating system will assist in meeting these requirements.

Today, processing power is becoming more and more expensive. Personal computers now possess computing power that rivals that of yesterday's mainframes. This extra computational bandwidth means that scanners can now perform more complicated processing (e.g. 3-D or ATL's SonoCT) that would not have been possible a couple of years ago. In the future, this will allow more and more complicated protocols and features to be added to the ultrasound cart.

2.3 Software

Of crucial importance to every ultrasound clinic is the ability to improve patient throughput. Furthermore, ultrasound machines are being used more frequently in many different clinical exams. This has meant that there is a big push to improve productivity and add to a growing number of clinical protocols.

Usability Initiatives

A large push has been made to automate the setting of parameters for both B-mode and Doppler imaging. Both GE and Acuson have introduced one-touch optimization. This provides clinicians with an easy and efficient means of optimizing the system setting, thereby increasing patient throughput. Greater emphasis is being placed on user interface design with the focus on ease of use, workflow and productivity gains. Going forward, usability issues are going to become more and more important, and will be the differentiating factor between machines.

Image-guided Therapy

The use of ultrasound in image-guided radiation therapy has recently seen application to prostate and breast treatment. The real-time nature of ultrasound makes it an ideal candidate for tracking an object such as a catheter within the body. Traditionally, image-guided therapy has relied on images acquired preoperatively, which has meant that any changes in the location or structure that occur during the operation are not seen. Ultrasound can allow rapid, up-to-date visualization of *in vivo* changes. Combining ultrasound with other modalities such as CT and MR will further improve its utility as an image-guided tool.

Harmonic Imaging

Harmonic imaging is becoming an integral feature of machines from ATL, GE, Toshiba and Acuson. The advantage of this imaging is that it improves image clarity by decreasing acoustic clutter and enhancing image contrast. Harmonic imaging is useful for looking at microvasculature, and effort is being focussed on developing contrast agents with appropriate half-lives.

Wider Field of View

Siemens introduced the concept of panoramic imaging technology, which enables radiologists to instantly see expansive views of internal organs. The clinical utility of this is that it provides the clinician with better side-by-side comparisons of anatomical structures such as both lobes of the thyroid. GE has followed suit with the introduction of its LOGIQ view, which also provides functionality similar to that offered by Siemens. Improved methods of stitching images together and the application of this technology to 3-D is a very real likelihood in the near future.

3-D and 4-D Ultrasound

As noted in the Working Group 4 report *Image Analysis and Visualization* (see Section 9), 3-D visualization techniques have been used in CT for many years. To date, the application of these techniques to ultrasound is relatively immature. Based on the physics of the ultrasound signal, techniques such as surface-based rendering are not as useful. For ultrasound, multiplanar reformatting and volume rendering have proved more clinically valuable. Today, 3-D ultrasound has found most of its use in obstetrics. Indeed, 3-D ultrasound has not found its way into everyday clinical use. For this to happen, 3-D reconstruction techniques must become faster and, moreover, this functionality must become fully integrated into the scanner system. It is crucial that the use of 3-D ultrasound does not slow down the throughput of patients in the clinic. In principle, 3-D imaging has the potential to improve patient throughput by allowing the clinician to acquire a single volume that can be reformatted at any orientation — a virtual transducer, as it were. With the introduction of 2-D arrays, acquisition of 3-D volumes should be simpler and faster.

2.4 Portability

In the last decade, high-end ultrasound machines have become bigger and more complex. The need for small, portable ultrasound machines has been recognized, with companies like ATL spinning off

SonoSite in 1998 to address this lucrative market. Small and affordable ultrasound scanners have the potential to reach a wider audience of clinicians and doctors. SonoSite's approach was to replace the 10–20 circuits boards found in a normal ultrasound scanner with four ASIC chips. The result is a fully functional ultrasound scanner that weighs only 2.4 kg.

More recently, a company called Terason took a different approach. Using charge-domain processing and ASIC technology, they were able to develop an ultrasound system completely housed in a scan probe. The result is a system that weighs only 10 ounces and connects to any PC computer with an IEEE 1394 (FireWire) interface.

The development of portable, low-cost ultrasound scanners is a step toward having a scanner in every doctor's office and/or clinic. In addition, these portable systems can be used in areas previously inaccessible to ultrasound scanners (e.g. battlefields and triage centers) and for rapid deployment to immobile patients.

2.5 Connectivity

Ultrasound scanners can no longer be considered stand-alone systems with no connection to the outside world. More and more hospitals are going digital, using large archives to store images. Ultrasound scanners must be able to communicate with the rest of the world. Indeed, companies such as Acuson and Agilent are offering workstation products such as KinetDx and Enconcert that offer users the ability to analyze off-line. Taking this a step further, one can expect physicians to require access to the images generated by the ultrasound machine in their office or at home via the Internet.

3. IMPORTANCE

There is a lot of competition in the ultrasound market. Medical doctors and technicians are demanding higher and higher image quality and more functionality from their ultrasound machines. Ultrasound machines are now relatively mature and soon the limits of physics will be reached. At that time, physicians will only be able to differentiate between systems based on cost and ease of use. With the health care industry becoming more and more cash constrained, it becomes important to be able to produce cost-effective ultrasound scanners while still maintaining image quality and system functionality.

4. CLINICAL REQUIREMENTS

Clinical requirements for ultrasound scanners include the following:

- real-time image capture and display;
- improved contrast and detail resolution;
- ease of use;
- connectivity via DICOM; and
- fully integrated duplex system with extensive functionality (for example, support for different transducers, harmonic imaging and in the future 3-D and even 4-D imaging for cardiology).

5. MATURITY AND RISK

Ultrasound scanners are already very mature and readily available. The existing technology provides a stable base upon which advances can be made.

6. AVAILABILITY

Ultrasound scanners of many varieties are available from many sources. Simple portable machines to very expensive systems can be obtained.

7. BREADTH OF APPLICATION

Ultrasound is used in almost all areas of medicine: obstetrics, vascular, cardiology, urology and many more. The introduction of harmonic imaging, image-guided functionality and 2-D arrays will provide additional usage for ultrasound scanners. The use of ultrasound scanners is pervasive in the medical community with no sign of diminishing.

8. IMPACT OF STANDARDS AND REGULATIONS

Standards and regulations in two areas will have an impact on what can and cannot be achieved by ultrasound scanners:

- the dosage (SPTA, TPSA, etc.) that regulatory bodies such as the U.S. Food and Drug Administration deem acceptable for certain exams; and
- DICOM working groups (e.g. WG12 and WG17) will dictate how the machine communicates data with the outside world.

9. REFERENCES

Image Analysis and Visualization. Report of Working Group 4, Medical Imaging Technology Roadmap (http://strategis.ic.gc.ca/medimage).

Acuson Corporation, Mountain View, California: http://www.acuson.com/index2.html.

Agilent Technologies, Boston, Massachusetts: http://www.agilent.com/healthcare/ultrasoundimaging.

Alliance Medical Inc., Montréal, Quebec. Contact Karim Menassa at (514) 344-3030.

ATL Ultrasound, Bothell, Washington: http://www.atl.com.

GE Medical Systems, Milwaukee, Wisconsin: http://www.gemedicalsystems.com/medical/ultrasound/index.html.

Hitachi Medical Systems, Tarrytown, New York: http://www.hitachiultrasound.com.

Siemens Ultrasound, Issaquah, Washington: http://www.siemensultrasound.com.

Sonocite, Bothell, Washington: http://www.sonosite.com.

Terason, Burlington, Massachusetts: http://www.terason.com.

Toshiba Medical Systems Co. Ltd., Tokyo, Japan: http://www.toshiba.com/tams/newtams/us/usset.html.

Scanner/Sonographer Interface

1. GOALS

Sonography has opened the door to many positive advances in diagnostic imaging for patients, and provided a stimulating career for sonologists (physicians) and sonographers (technologists and nurses). Unfortunately, the modality presents a health threat to the operators because of equipment ergonomics and the manner in which examinations are performed. Surveys in North America and Australia have documented health risks such as repetitive strain injury (RSI) or musculoskeletal injury (MSI), and there has been gradual recognition of the prevalence of MSI in the diagnostic ultrasound workplace. This discussion will review current concerns with ultrasound equipment design and suggest priorities for future ergonomic research and development to prevent workplace-related sonographer injuries.

Further research into causes of sonographer MSI will be valuable, as measurement of variables is difficult. For example, there is variation among sonographers with regard to body fitness, approach to scanning technique, workstation configuration, examination duration and mix, and specialties practised.

2. DESCRIPTION

The nature of the examination and configuration of the technology (i.e. monitors, instrumentation panels and handheld transducers), including ancillary equipment (i.e. VCR, hard copy printer and camera, and electronic image file systems) will be discussed. Nontechnical equipment (such as stretchers and chairs) and the workplace environment (characterized by, for example, ambient lighting, workloads and frequency of breaks) will also be touched on.

3. IMPORTANCE

The Canadian Society of Diagnostic Medical Sonographers (Work, Health & Ergonomics Survey, Nov. 1999) reports a high prevalence of work-related musculoskeletal symptoms among respondents:

- 87 percent had pain and discomfort at some time during their career, for an average period of four years;
- majority of symptoms involved the shoulder (54 percent), neck (37 percent), wrist (25 percent) and upper back (25 percent);
- 14 percent of survey respondents with pain submitted a workers compensation claim; 61 percent of these claims were accepted; and
- 10 percent of respondents reported absence from work with an average of 25 consecutive work days missed due to MSI.

Data from a pilot study in Washington and Oregon in 1996 found that "18% of respondents suffered no symptoms, 66% suffered symptoms without RSI, and 15% have been diagnosed with RSI." The analysis revealed that a positive correlation exists between certain ergonomically unsound work habits and increased symptomatology. The proportion of sonographers diagnosed with RSI tended to increase as the number of years in the profession increased. The reporting rate of musculoskeletal symptomatology and RSI also appeared to be influenced by other variables, such as gender, workload, and stress in the workplace."

In Sydney, Australia, a survey (McFarlane 1997) of sonographers at the Royal Prince Alfred Hospital working in general, obstetrics/gynecology, and vascular and cardiac ultrasound sections revealed that 78 percent of sonographers suffered symptoms of work-related MSI.

A review of several surveys conducted in various parts of the world confirms a high incidence of MSI in the sonographer workforce. Performance of any one (or more) diagnostic ultrasound examination (i.e. echo, obstetrics, vascular, abdomen, small parts or neonatal) can lead to symptoms of MSI. Musculoskeletal symptoms are aggravated by sustained pinch grasp of small transducers, repetitive minute transducer manipulation, sustained pressure of the transducer against the patient's body, sustained shoulder abduction, sustained and repetitive twisting of the neck, trunk or both, awkward sustained postures and insufficient recovery time (breaks). Awkward posture (as with portable examinations or poor layout of an exam room), high daily workload, and years of service all play a role.

Musculoskeletal injury in the sonographer workforce with the resultant lost work days has a significant negative impact on the delivery of health care in an environment of high demand and limited resources for ultrasound services. There is a severe shortage of trained sonographers, coupled with expanding ultrasound demand due to technology advances (i.e. cardiac, vascular, musculoskeletal and interventional) in addition to increased requests for established examinations. Diagnostic ultrasound is an investigative tool used early in the diagnostic process by physicians. Lack of timely access to ultrasound resources causes treatment delays and added expense in patient diagnosis (i.e. duplication of testing, longer hospital stay and prolonged patient discomfort). To an already limited sonographer workforce and high demand, there is added the risk and impact of MSI among sonographers.

In Canada, data on workers' compensation MSI-related claims made by sonographers is not available due to the methods of data collection. However from sonographer surveys in North America, anecdotal information suggests claims do occur and are likely to increase as sonographers, employers and physicians increase their knowledge of MSI.

Aside from the issues mentioned, there is a difficult personal course of recovery and real possibility of career loss for individual sonographers suffering from MSI. Many affected sonographers continue working in pain and have a decreased ability to perform regular work duties. The pain and discomfort extend to situations outside the workplace, limiting activities at home and during recreation.

Ultrasound is an expanding technology and the need for sonographers is increasing. Ultrasound examinations are highly subjective and must be performed by trained personnel who have met a standard of practice. Managers, sonographers, and manufacturers involved in the health care industry must guard against losing sonographers to MSI.

4. CLINICAL REQUIREMENTS AND RECOMMENDATIONS

The prevention of MSI is a responsibility jointly shared by sonographers and managers. Both groups need an educated approach to MSI and to adopt preventive measures with regard to equipment placement and set up, workload and rest periods, and personal factors such as physical conditioning. Manufacturers need to be aware of MSI problems and provide user-friendly design when possible. It is recognized that perhaps there are no perfect ergonomic design solutions due to the nature of ultrasound examinations.

Given that surveys and research indicate the body regions most susceptible to MSI are the shoulders, fingers, neck and back, perhaps special attention should be given to the design of monitors, front-panel controls, and transducers and cables. Suggested design parameters are listed below by device or use.

Device	Need
Monitors	Adjustable for operator-screen distance, angle, swivel and height (sit and stand); resolution technology optimized for the human eye to discern detail without eye strain
Keyboard	Easily accessible controls; adjustable control panel positions; knobs, dials and buttons appropriate for function; minimal steps to achieve task
Transducers	Light weight cables and transducers; comfortable transducer shape for operator's grip and patient comfort; optimal cable and transducer storage
Scanner	Light weight; small size; easily maneuverable (with castors and handles); on-board storage of ancillary equipment with front-panel operation; cable management; quiet operation; low heat dispersion; footrest
Scan Bed	Bed height adjustable (21" to 32"); Trendelenburg and reverse T.; head end upright adjustable; scan beds with side rails that move under the bed, thereby facilitating patient positioning at the edge of the mattress; removable echo window cushion

5. MATURITY AND RISK

Ultrasound scanners are a product with a high degree of maturity in terms of purpose and functionality. Equipment purchase is always a compromise of features, with image quality usually the first consideration and ergonomics ranking second. The necessary technology and knowledge exist to enhance the user-friendliness of scanners. However, it can be said that the ergonomics of sonography has not advanced significantly since the early years of real-time sonography. Purchasers need to demand that the user interface improve, and this will occur as managers become more aware of the costs of MSI.

6. AVAILABILITY

Ultrasound scanners are available from many vendors, who offer products to meet many needs. Some products offer greater ergonomic comfort than others.

7. BREADTH OF APPLICATION

The technology is applied in diagnostic medical imaging. Many medical specialties rely on diagnostic ultrasound, with examinations frequently performed by departments other than the traditional radiology department (e.g. vascular, cardiac, obstetrics and surgery).

8. COST-BENEFIT ANALYSIS

It is in the best interest of a manufacturer to design equipment to be user friendly, as it increases desirability of the product.

9. IMPACT OF STANDARDS AND REGULATIONS

Currently, regulations for ultrasound scanners apply to power output of scanners, ensuring that patients are kept safe from possible biological damage from high-frequency ultrasound (United States, Food and Drug Administration).

Regarding operator and scanner ergonomics, it is desirable that sonographer associations, vendors, and perhaps government stakeholders collaborate to develop and constantly review ergonomic guidelines for the manufacture of ultrasound scanners.

10. REFERENCES

Canadian Society of Diagnostic Medical Sonographers: http://www.csdms.com.

Canadian Society of Diagnostic Medical Sonographers and Healthcare Benefit Trust. November 1999. *Work, Health & Ergonomics Survey*. Vancouver.

Necas M. 1996. "Musculoskeletal symptomatology and repetitive strain injuries in diagnostic medical sonographers: A pilot study in Washington and Oregon," *Journal of Diagnostic Medical Sonography*, 12: 266–273.

Ogram D. May 1995. *Ergonomic Evaluation of Work Performed By Sonographers While Conducting Ultrasound Examinations* (Saskatchewan: Occupational Health & Safety Division, Saskatchewan Labour).

Pike I, Russo A, Berkowitz J, Baker J, Lessoway VA. September/October 1997. "The Prevalence of Musculoskeletal Disorders Among Diagnostic Medical Sonographers," *Journal of Diagnostic Medical Sonography*, 13: 219–227.

Society of Diagnostic Medical Sonographers: http://www.sdms.org/msi.

Stevens D. April 11, 1994. *Repetitive Strain Injuries and Cardiac Sonographers.* Calgary: Foothills Hospital.

11. FURTHER READING

Gregory V. September 1998. "Musculoskeletal Injuries: Occupational Health and Safety Issues in Sonography," *Sound Effects 30.*

Habes DJ, Barton S. 1999. *Health Hazard Evaluation Report*. 99-0093-2749.

Magnavita N, Bevilacqua L, Mirk P, Fileni A, Castellino N. 1999. "Work-related musculoskeletal complaints in sonologists," *Journal of Occupational and Environmental Medicine*, 41: 981–988.

Melzack R. 1975. "The McGill Pain Questionnaire: major properties and scoring methods," *Pain*, 1: 277–299.

Mirk P, Magnavita N, Masini L, Bazzocchi M, Fileni A. October 1998. "Frequency of Musculoskeletal Symptoms in Diagnostic Medical Sonographers. Results of a Pilot Survey," *Radiol Med*, 4: 236–241.

NIOSH Technical Report, HETA 99-0093-2749

Pransky G, Feuerstein M, Himmelstein J, Katz JN. 1997. "Development and validation of the Upper Extremity Function Scale," *Journal of Occupational and Environmental Medicine*, 39: 1195–1202.

Schoenfeld A, Goverman J, Weiss DM, Meizner I. 1999. "Transducer user syndrome: an occupational hazard of the ultrasonographer," *European Journal of Ultrasound*, 10: 41–45.

Sjøgarrd G, Søgaard K. 1998. "Muscle injury in repetitive motion disorders," *Clinical Orthopaedics and Related Research*, 351: 21–31.

Smith and Sainfort (1989) in Kuorinka et al. (eds). 1995. *Work-Related Musculoskeletal Disorders: a Reference for Prevention*. Philadelphia: Taylor & Francis.

Smith AC, Wolf JG, Xie GY, Smith MD. 1997. "Musculoskeletal pain in cardiac ultrasonographers: results of a random survey," *American Society of Echocardiography*, 10: 357–362.

Vanderpool HE, Friis EA, Smith BS, Harms KL. 1993. "Prevalence of carpal tunnel syndrome and other work-related musculoskeletal problems in cardiac sonographers," *Journal of Occupational Medicine*, 35: 604–610.

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Medical Imaging Technology

WG 2 - Final Working Group Report

APPENDICES

- A: Steering Committee
- B: Working Group 2 Membership List
- C: Critical Technology Template

APPENDIX A

Medical Imaging Technology Roadmap Steering Committee

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APPENDIX C

Critical Technology Template

1. TECHNOLOGY WORKING GROUP:
WG name.

2. CRITICAL TECHNOLOGY:
Technology name.

3. RANKING:
Rank of this technology among the technologies investigated by the WG (i.e. 3/5).

4. GOALS:
The performance goals of the technology: - are driven by customer requirements; - should be defined in quantitative and qualitative terms (without disclosing proprietary information); - include economic (cost, etc.), time (cycle time improvements, etc.), and physical property considerations.

5. DESCRIPTION:
Brief technical description of the technology.

6. IMPORTANCE:
Why is the technology critical (e.g., regulatory requirements, customer demands, financial and other competitiveness issues); when is the technology required; to whom is the technology critical; what happens if the technology is not available or implemented.

7. CLINICAL REQUIREMENTS:
What clinical requirements must the technology satisfy?

8. ALTERNATIVES:
Other technologies, non-technological solutions, product substitution, etc. - Each WG should be familiar with the technologies under investigation by the other WGs, so that linkages can be made among alternative or competing technologies.

9. MATURITY AND RISK:
- What can the technology do today; - What incremental capabilities are required to produce the products required for the 2001 through 2005 time period; and - What risks are associated in obtaining these incremental capabilities.

10. AVAILABILITY:
Where is the technology currently available, from whom, how, cost considerations, etc.

11. BREADTH OF APPLICATION:
How broadly can the technology be applied: which areas of the medical imaging industry, what other industry sectors, etc.

12. COLLABORATORS:
Potential sources of help in developing or acquiring, and implementing the technology: Examples: NRC, primes working with suppliers, etc.

13. COST-BENEFIT ANALYSIS:
Costs could include technology development or acquisition, and implementation. Benefits are based on an estimate of market usage of the enabling technology.

14. REFERENCES:
List of pertinent documents.

15. CONTACTS:
Resource persons for further information.

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